bionet

Electrocardiograph

Cardio P1

Operation Manual

Ver. 1.02

2024. 02. 01

bionet

REVISION HISTORY

Revision No.	Date	Contents	Page
1.00	2022.05.24	First Written	All
1.01	2023.04.04	Modified to model name Cardio P1 Full translation reflected Change logo Correction of incorrect information (delete 'LAN network, WLAN network')	All
1.02	2024.02.01	Update European Sales email and web address	All

Caution
Federal law restricts this device to sale by or on the order of a physician

Note
The product does not have shelf life. Its expected use life is 3 years. After 3 years, though the product still works normally, it is recommended to have it checked by Bionet.

※ In the event of a malfunction or failure, contact Service Dept. Of Bionet Co., Ltd. along with the model name, serial number, date of purchase and explanation of failure.

Paid Services

A fee will be charged for all services except for breakdowns, so be sure to read this operation manual below before putting in a request.

- Usage description and simple inspection without disassembly - In case of reinstallation due to poor installation by a distributor	Free the 1st time Charged starting the 2nd time
- Inadequate installation or loosening due to physical product movement, relocation, etc. - When re-installing after the first installation requested by the customer at the time of purchase - When reinstallation is required due to inexperienced installation by the customer - When a service is requested due to the input of foreign substances or improper cleaning	Charged starting the 1st time

1. Equipment cleaning, adjustment, and usage description are not product breakdowns.
(Unfeasible repairs are subject to separate standards.)

2. Breakdowns caused by consumer negligence
Breakdowns and damage due to careless handling by the customer or incorrect repair are caused by:
- Using incompatible electric capacity.
- Mishaps such as dropping the product.
- Using the third party replacements or options not specified by our company.
- Non-Bionet technicians or agency technicians in the process of repair.

3. Other cases
- Breakdowns by natural disasters (fire, salt damage, flood damage, earthquake, etc.)
- When a consumable part has reached the end of its life (accessories)

Warnings, Cautions, and Notes

- The following terms are used throughout this manual to emphasize important and critical information. You must read these statements to help ensure safety and to prevent product damage.

- The manufacturer or the product distributor is not liable for any loss or damage to the product caused by incorrect use or negligence in product maintenance.

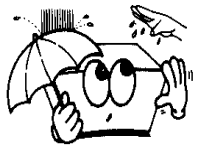
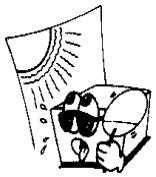
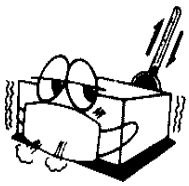
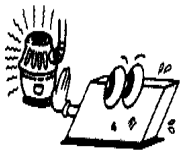
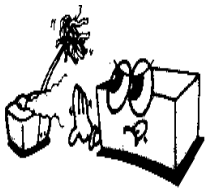
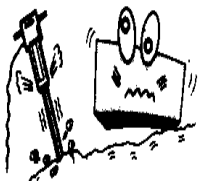
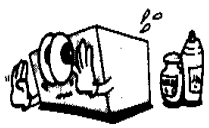
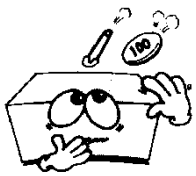
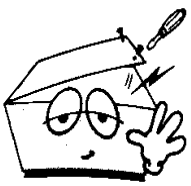
Warning
Warning Failure to follow this message may cause severe injuries, casualty or physical damage to patients.

Caution
Caution Failure to follow this message may cause in non-life-threatening injury or damage to the equipment.

Note
Note indicates some important information and tips, which are not dangerous, about installation, operations and maintenance.

General Precautions on Environment

DO NOT store or operate the equipment in the places listed below.

	A place exposed to moisture (DO NOT touch the equipment with wet hands.)		A place under direct sunlight
	A place in areas with highly fluctuating temperatures.		A place in the vicinity of Electric heater
	A place with excessive humidity rise or poor ventilation		A place with sources that cause excessive shock or vibration
	A place exposed to chemicals or at risk of gas leakage		Avoid the invasion of small objects/ particles such as dust, and especially avoid metallic material.
	DO NOT disjoint or disassemble the equipment. (Bionet is not liable for broken products caused by attempted disassembly.)		DO NOT connect power until the product is completely installed. It may cause damage to the product.

Safety Instructions for Electricity

Please note the following precautions before using the product.

- Is the power supply cord proper?

  1. Cardio P1 : 5Vdc, Max. 0.5A
- Is every cord connected properly to the product?
- There is a risk of electric shock if the Rest stand of the equipment is damaged or not be fixed to the equipment body. Do not use the product and immediately ask the manufacturer or seller for repairs.

Classification

- This equipment is classified in accordance with IEC 60601-1 as follows.
- Class I protection against electric shock and Type CF defibrillation-proof
- Compatibility Requirements standard-: Parts
- Degree of protection against harmful ingress of water: Ordinary
- DO NOT use this product near flammable anesthetic or solvents.
- Continuous operation
- IEC/EN 60601-1-2 (Electromagnetic Compatibility Requirements) standard:

Type	Description
Class A	The equipment or system is suitable for use in all establishments. It requires a higher amount of power than the public low-voltage power supplied to typical residential buildings. Mains power should be typical commercial or hospital environment.

Note
Diagnosis provided by CardioP1 must be confirmed by a qualified medical professional.

Note
The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such

as relocating or re-orienting the equipment.

Caution	
	Warning: MR-unsafe! DO NOT expose the device to a magnetic resonance (MR) environment. • The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core. • Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning. • The device may generate artifacts in the MR image. The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

Safety Messages

The following messages are applied throughout the product. Certain statements may also appear elsewhere in the manual.

WARNING:

ACCIDENTAL SPILLS — If the equipment is penetrated with liquid, take it out of service and have it checked by a service technician before using it again.

DO NOT allow liquids to enter the equipment to prevent electric shock or equipment malfunction.

WARNING:

CABLES - To avoid possible strangulation, route all cables away from the patient's throat.

WARNING:

CONNECTION TO MAINS - This is class I equipment.
The mains plug must be connected to an appropriate power supply.

WARNING:

DEFIBRILLATOR PRECAUTIONS - Avoid physical contact with the patient during defibrillation, as it may cause serious injury or death.

Patient signal inputs labeled with the CF symbols with paddles are protected against damage resulting from defibrillation voltages.

The defibrillator paddles in relation to the electrodes should be placed properly to assure successful defibrillation.

Use only recommended cables and leads to ensure adequate defibrillation protection.

WARNING:

ELECTRODES - Polarized electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. Residual charge blocks ECG signal acquisition.

Use non-polarized electrodes (silver or silver chloride construction) for ECG monitoring with each defibrillation.

WARNING:

MAGNETIC AND ELECTRICAL INTERFERENCE - Magnetic and electric fields may interfere with the proper operation of the equipment.

Therefore, make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements.

X-ray equipment or MRI devices are possible sources of interference as they may emit higher

levels of electromagnetic radiation.

WARNING:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING:

EXPLOSION HAZARD - Do NOT use in the presence of flammable anesthetics vapors or liquids.

WARNING:

INTERPRETATION HAZARD - Computerized interpretation is only significant when used in conjunction with clinical findings.
A qualified physician must verify all computer-generated diagnoses.

WARNING:

OPERATOR - Medical technical equipment such as this system must be used only by qualified and trained personnel.

WARNING:

SHOCK HAZARD - Improper use of this equipment may cause electric shock.

Strictly observe the following guidelines.

Failure to do so may endanger the lives of the patient, user, and bystanders.

To disconnect the equipment from the power line, first remove the power plug from the wall outlet before disconnecting the cables from the equipment; Otherwise, there is a risk that metal parts inadvertently inserted into the power cord socket will come into contact with line voltage.

Additional devices connected to medical electrical equipment shall comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment).

Additionally, all configurations must comply with the requirements for medical electrical system. (See IEC 60601-1-2 or Clause 16 of IEC 60601-1)

Anyone who connects additional devices to medical electrical equipment is in the position of configuring medical system, and is responsible for complying with the requirements of medical electrical system.

Keep in mind that local legislation takes precedence over the above-mentioned requirements.

If in doubt, consult your local distributor or the technical service department.

WARNING:

SITE REQUIREMENTS - Improper placement of the device and/or accessories may result in a hazard to the patient, operator, or bystanders.
Do not route cables in a way that they may present a stumbling hazard.

For safety reasons, all connectors for patient cables and lead-wires are designed to prevent inadvertent disconnection, should someone pull on them.

For devices installed above the patient, adequate precautions must be taken to prevent them from dropping on the patient.

WARNING:

TREADMILLS - Avoid rapid changes in treadmill speed and/or grade during a stress test.

WARNING:

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer.

CAUTION:

PROPER LEADWIRE CONNECTION - Improper connection will cause inaccuracies in the ECG. Trace each individual lead-wire from its acquisition module label to the colored connector and then to the proper electrode to ensure that it is matched to the correct label location.

CAUTION:

ACCESSORIES (SUPPLIES) - The parts and accessories used must comply with the requirements of the relevant IEC 60601 series safety standards and essential performance standards, and/or the system configuration must meet the requirements of the IEC 60601–1-2 medical electrical system standards.

CAUTION:

ACCESSORIES (EQUIPMENT) - The use of accessory equipment that does not comply with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Considerations related to the choice of equipment shall include:

• Use of the accessory in the patient vicinity, and Evidence that the safety certification of the accessory has been performed in accordance with the appropriate IEC 60601–1 and/or IEC 60601-1-2 harmonized national standard.

CAUTION:

BEFORE INSTALLATION — Compatibility is critical to safe and effective use of this equipment. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

CAUTION:

DISPOSABLES - Disposable devices are intended for single use only. They should not be reused as performance may degrade or contamination could occur.

CAUTION:

DISPOSAL — At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with local, state, or federal guidelines regulating the disposal of such products. If you have questions concerning the disposal of the product, please contact Bionet or its distributor.

CAUTION:

EQUIPMENT DAMAGE — Equipment intended for emergency application must not be exposed to low temperatures during storage and transport to avoid moisture condensation at the application site. Wait until all moisture has vaporized before using the equipment.

CAUTION:

ELECTRIC SHOCK — To reduce the risk of electric shock, do not remove cover or back of the equipment. Refer servicing to qualified personnel.

CAUTION:

OPERATOR — Medical technical equipment such as this electrocardiograph system must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.

CAUTION:

POWER REQUIREMENTS - Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label. If this is not the case, do not connect the system to the power line until you adjust the unit to match the power source.

This equipment is suitable for laptop's USB power connection.

Equipment connected to the ECG system and in the patient, environment must be powered from a medically isolated power source or must be a medically isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ECG system.

CAUTION:

SERVICEABLE PARTS - This equipment contains no user serviceable parts.

Refer servicing to qualified service personnel.

CAUTION:

SUPERVISED USE - This equipment is intended for use under the direct supervision of a licensed health care practitioner.

Safety Symbols

Symbols	Contents
	Attention Consult accompanying documents
	Consult Instructions for Use: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the equipment.
	Safety Sign To signify that the instruction manual must be read. Reading the instruction manual before starting work or before operating equipment.
	General Prohibition Sign
	Defibrillation Proof-Type CF APPLIED PART
	ECG Patient Cable Connector
	USB Connector

Symbols	Contents
	Auto operation / Event Marker Key
	Power (USB data) cable insertion direction indication
	Power (USB data) cable connection indication

	Manufacturer		
	Authorized Distributor in the European Community		
	Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.		
	MR Unsafe: DO NOT use this equipment in all MR environment.		
	No sterilization		Do not use if package is damaged
	Recycling; Dispose of properly in accordance with all state, province, and country regulations		This way up. For the duration of shipping/delivery, the carton should face upright
	Fragile; Handle with care		Use no hooks; Absolutely no hand hooks should be attached to pull the parcel
	Keep away from rain		

Specifications or functions indicated on user manual are subject to change without notification for the improvement of product.

Chapter 1. General Rules

1) Product Overview

1-1) Intended Use

The Cardio P1 Analysis System is intended to acquire, analyze, display, and record ECG information from adult and pediatric populations. The system provides 12-lead ECG and interpretive analysis. The 12-Lead ECG interpretation algorithm provides analytical information about the patient's heart condition, which must be confirmed by a qualified medical professional along with other relevant clinical information. Sending and receiving ECG data to and from the Hospital Information System is optional. The Cardio P1 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.

1-2) Indications

The ECG has proven to be among the most useful diagnostic tests in clinical medicine. It is now routine in the evaluation of patients with implanted defibrillators and pacemakers, as well as to detect myocardial injury, ischemia and the presence of prior infarction as well. In addition to its usefulness in ischemic coronary disease, the ECG is of particular use in the diagnosis of disorders of the cardiac rhythm and the evaluation of syncope.

1-3) Contraindications

There are no absolute contraindications to performing an ECG other than the patient's refusal. Some patients may be allergic or, more commonly, sensitive to the adhesive used to attach the electrodes. In this case, use hypoallergenic alternatives available from various manufacturers.

1-4) Side Effects

The ECG is a safe test that does not cause health complications. There are no medical conditions associated with increased risk or adverse side effects of ECG.

1-5) Warnings, Cautions and Adverse Reactions

a. Modifications to this equipment are not allowed. Any unauthorized changes to the Cardio P1 device may compromise product safety and/or data and as such Cardio P1 cannot be held responsible and the equipment will no longer be supported.
b. The Cardio P1 is not designed as sterile equipment. Always follow the safety instructions given by the manufacturer of cleaning and disinfectant chemicals.
c. Do not expose the Cardio P1 to liquids.
d. The Cardio P1 should not be used in the presence of flammable liquids or gases, dust, sand, or any other chemical substances.
e. The Cardio P1 should never be outside accuracy limits.
f. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Cardio P1.
g. Maintenance must not be performed while the device is in use by a subject.
h. Use of accessories and cables other than those specified or provided by Cardio P1 for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Cardio P1 and result in improper operation.
i. Non-medical equipment must be kept outside the subject environment i.e. any area in which intentional or unintentional contact between the subject and parts of the system, or

some other persons touching part of the system, can occur.

j. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be more than 30cm (12 inches) away from any part of the Cardio P1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

k. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

l. Only use the Cardio P1 with the power supply provided. Attempted use with other power sources may cause irreparable damage and invalidate the warranty.

2) Recording ECGs during Defibrillation

This equipment is protected against the effects of cardiac defibrillator discharge to ensure recovery, as required by test standards. The patient signal input of the acquisition module is defibrillation-proof, therefore, it is not necessary to remove the ECG electrodes prior to defibrillation.

When using stainless steel or silver electrodes a defibrillator discharge current may cause the electrodes to retain a residual charge causing a polarization or DC offset voltage.

This electrode polarization will block the acquisition of the ECG signal. To avoid this condition, use non-polarized electrodes, which will not form a DC offset voltage when subjected to a DC current, such as silver/silver-chloride types if there is a situation where there is a likelihood that a defibrillation procedure will be necessary.

If using polarized electrodes, disconnect the lead-wires from the patient before the shock is delivered. Electrode defibrillation recovery is the ability of the electrode to allow the ECG trace tore turn after defibrillation. It is recommended to use non-polarized disposable electrodes with a Defibrillation Recovery class as specified in AAMI EC12 4.2.2.4. AAMI EC12 requires that the polarization potential of an electrode pair does not exceed 100mV, 5 seconds after a defibrillation discharge.

3) Product Characteristics

- Waves of ECG in 12 channels are configured with various channels in 3 channels + 3 rhythms, 3 channels + 1 rhythm, 6 channels + 1 rhythm, 12 channels, and 6 channels + 1 rhythm (ST Map) and reports are printed on the PC.
- Rhythm in 1 channel is acquired for a long time (1, 3, 5, 10, 20 and 30min) and reports are printed on the PC.

- The 12 channel rhythms are continuously printed simultaneously in real time.
- The heart rate, PR interval, RR interval, QRS interval, QT interval, QTc interval, P-R-T axis, and SV1/RV1/R+S size required for diagnosis are automatically calculated and provided on the report along with the ECG.
- Automatic ECG diagnostic results for pediatrics and adults are provided.
- Real-time detection of 13 kinds of arrhythmia is provided.
- A Disclosure function is provided to save and show ECG data up to 30 minutes. The Disclosure function helps diagnose an arrhythmia.
- Once an ECG is saved, you can change its filter settings, gain, print speed, channel configuration and rhythm settings, and print it out, which is helpful for diagnosis.
- It is available to enter and show on screen patient or user information making it feasible to efficiently manage the chart.
- The number of patient data stored varies depending on the PC capacity, and the stored data can be moved to another PC. In addition, additional storage and data movement are possible in USB memory.
- Various protocols are supported to enable connection with the hospital computer network (EMR, PACS, etc.), and File and Worklist DB functions have been enhanced.

4) Product Configuration

The Cardio P1 system is comprised of the following components.

Cardio P1

1) CardioSync

- Software that analyzes and records the measured ECG
- Installed on a PC.

2) Cardio P1

- Device to ECG measurement

Basic Configuration and Accessories

Make sure to open the package box and see if the following components are contained. In addition, make sure to see if body or components are damaged.

① Body (1ea)

- Cardio P1 90.75(W) x 103.5(H) x 24.93(D)mm

② Patient Cable (1ea) - Length 1,400mm (Max)

③ Power (USB Data) Cable (1ea) - Length 2,450mm (Max)

④ Limb Electrodes (1set)

⑤ Chest Electrodes (1set)

⑥ Hanger (1ea)

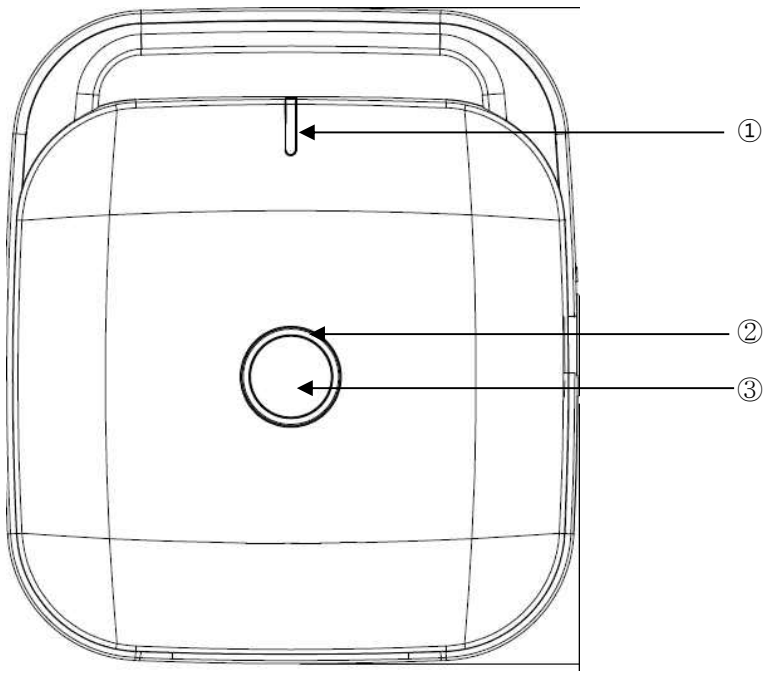
⑦ Silicone Pad (1ea)

⑧ USB Lock Key (1ea)

⑨ ECG Gel (1ea)

Cardio P1 Body Configuration

▣ Top View

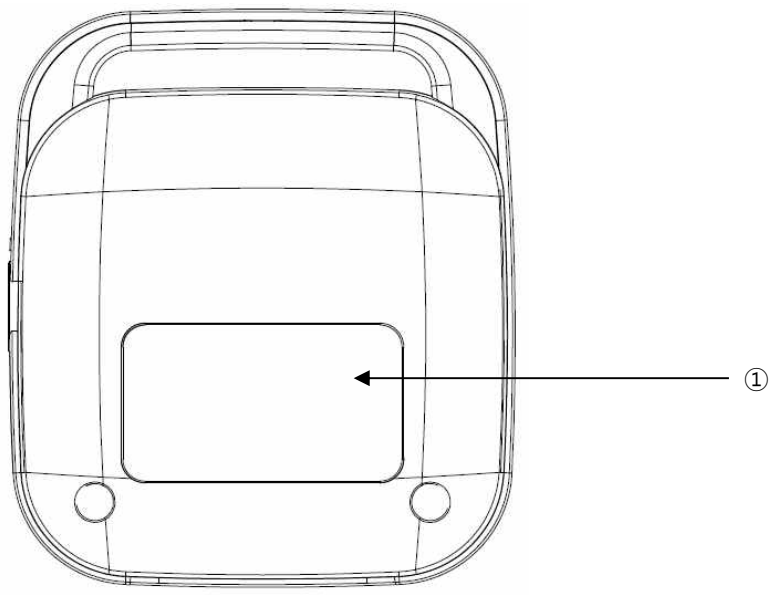


① Power Indication Part (LED) : Part showing the power connection status of a product

② Lead fault Indication Part (LED) : Part that informs the lead connection status

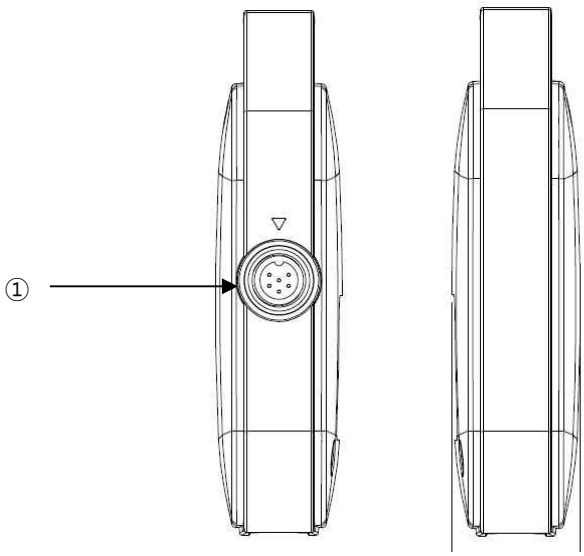
③ Function Switch : Auto operation (push more than 3 seconds), event marker key

▣ Bottom View



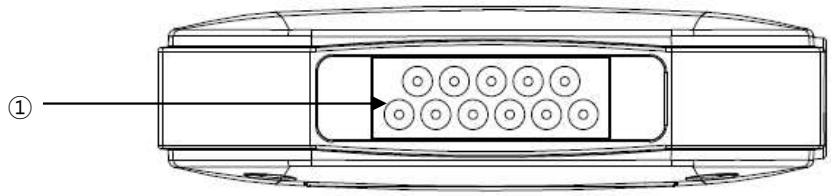
① ID Label : Part to attach ID Label

▣ Side View



① Power (USB Data) Cable Connection Port

▣ Rear View



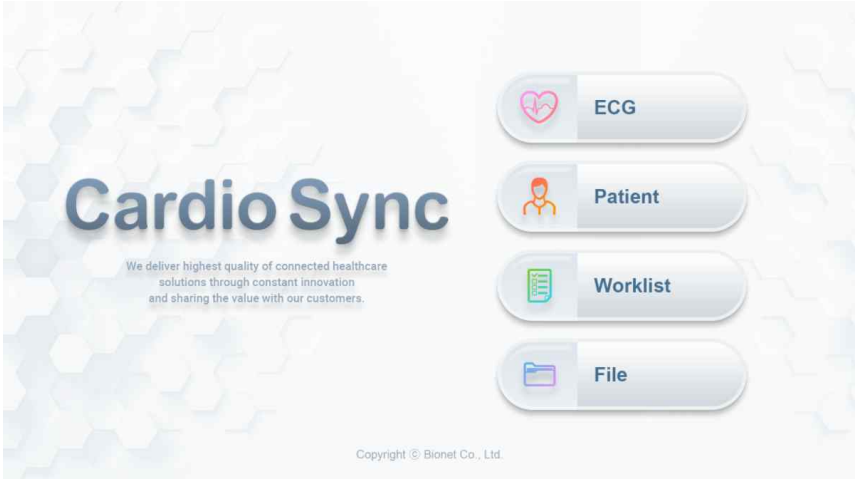
① ECG Cable Connection Port

Warning
There is a risk of electric shock if the Rest stand of the equipment is damaged or cannot be fixed to the equipment body. Do not use the product and immediately ask the manufacturer and the seller for repair.

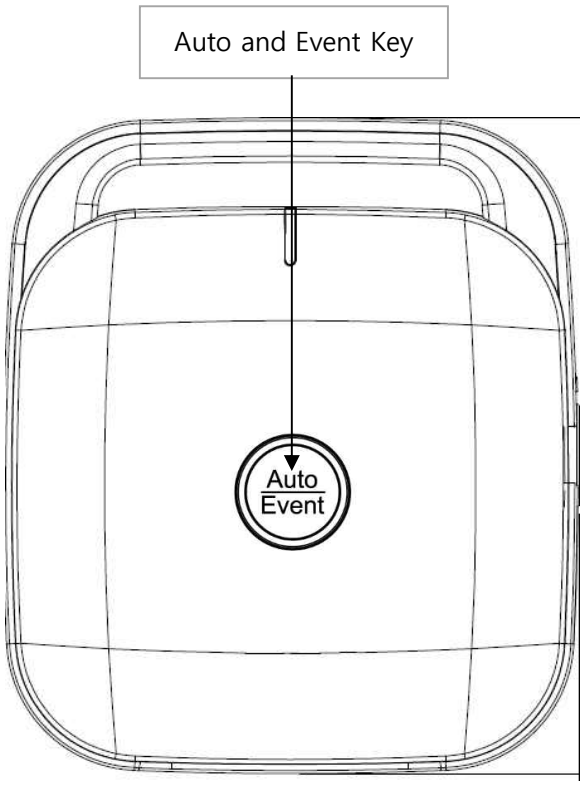
Note
Do not open the cover of the equipment; it may cause an electric shock. Repair or disassembly of the equipment can only be performed by those who have product repair qualifications recognized by Bionet.

Caution
When using the device (Cardio P1) connected to the PC, the mouse may malfunction. In this case, reconnect the device's power (USB) cable to the PC.

CardioSync Main Screen

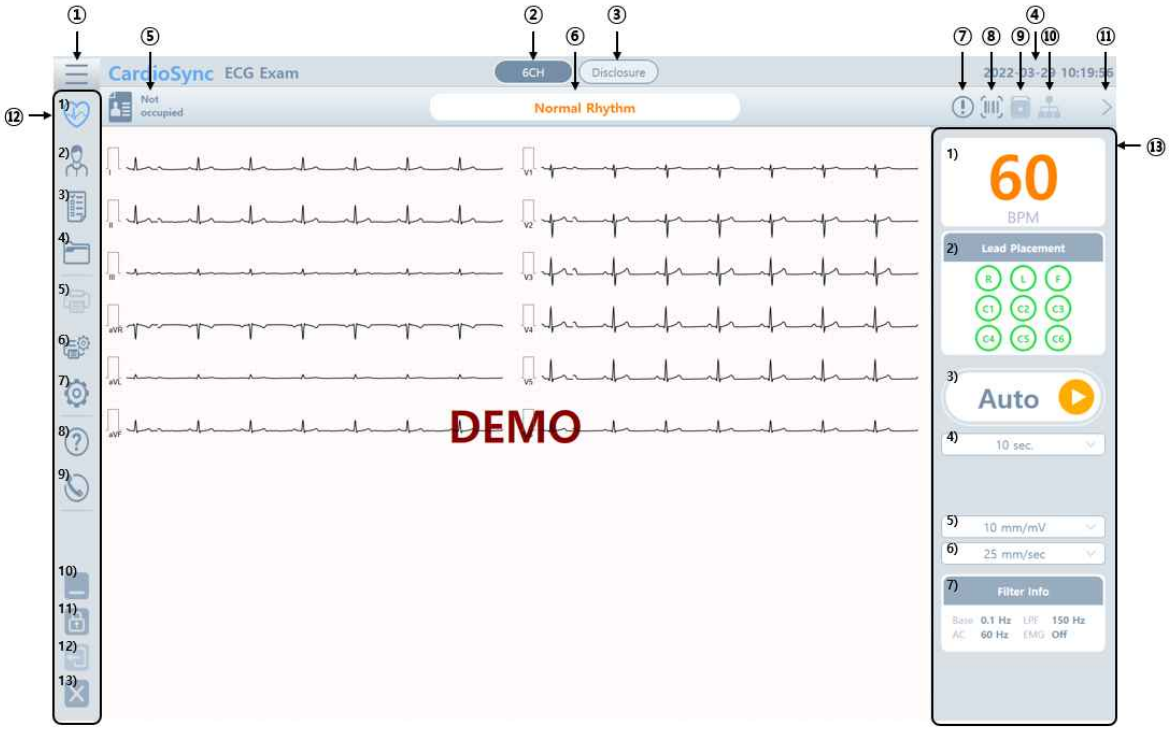


Graphic Display Window



ECG Graphic Window

Explain the contents displayed in the graphic window.



① Button for expand/collapse Quick Menu

② 6CH display button

③ Disclosure button

④ Display the current date or time

⑤ Menu button for indicating patient ID and name and entering patient information

⑥ Display the real-time diagnosis name display

⑦ Indicate Retry queue (sending failure list management) icon

⑧ Access status of external devices (barcode reader)

⑨ Access status of Cardio P1

⑩ Menu button for network connection status and setup

⑪ Button for expand/collapse Side Menu

⑫ Quick Menu bar

1) Button for moving to ECG

2) Button for moving to Patient list

3) Button for moving to Worklist

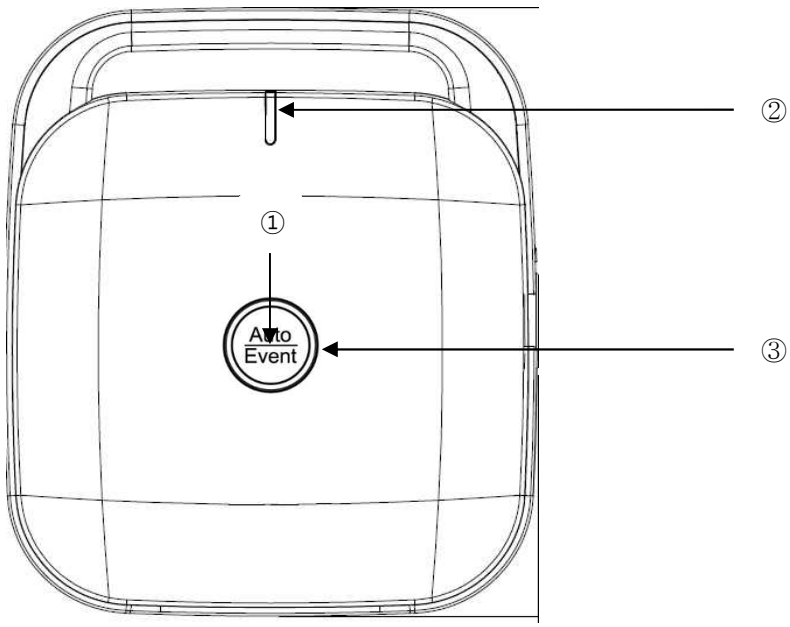
4) Button for moving to File
5) Print button
6) Print setup menu button
7) Setup menu button
8) Display manual button
9) Show manual
10) Minimize button
11) Show contact us
12) Logout button
13) Close button

⑬ Side Menu bar

1) Indicate heart rate
2) Lead Fault status display and lead position display window button
3) AUTO button
4) Menu button for indicating ECG record mode (one of the 10s, 1m, 3m, 5m, 10m, 20m and 30m) and setup
5) Menu button for indicating or setting up signal size
6) Menu button for indicating or setting up print speed
7) Set filter value display window

Note
The detection range of heart rate is 30-300 bpm with ± 3bpm of error range.

Function Key Panel



▣ Button

①		Auto / Event. 1. Long Press (more than 3 seconds) Perform the operation that is the most frequently performed in the saving, transmission, and printing of data in the ECG diagnosis test with one key 2. Short Press Performed to mark as a marker when abnormalities such as arrhythmias were felt in the ECG diagnostic test

▣ Indicating light

②		Indicate the DC power connection status. blue LED light turns on when DC power is connected on the equipment body.
③		Indicates the lead fault status when the patient cable is connected. The red LED is lit when in a lead fault condition. When everything is connected, the blue LED indicator lights up.

5) Installing System

Installation Precautions

Note the following when installing the Cardio P1

- Use the equipment within the ambient temperature of 10~40℃ and humidity of 30~85%.
- Check the connection of the power cord and handle the patient cable with care.
- Handle the equipment with care as it is sensitive to impact.
- Install the equipment in a place with proper ambient temperature and humidity, and away from dust and flammable materials.

Software Minimum Requirement

Install the program on a PC that meets the minimum specifications below.

Operation System	Window 10
CPU	Core2Duo 1.86GHz
RAM	2 GB
Graphics Adapter	VGA RAM 256 MB 1,600 x 900
Hard Drive	500 GB
LAN Speed	10 Mbps
# of USB	2

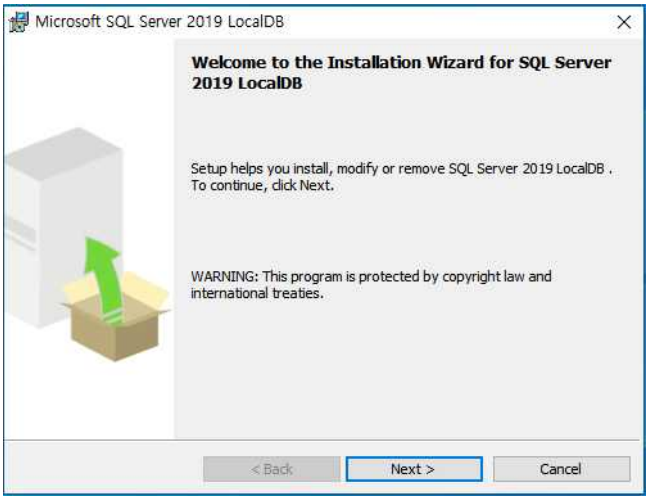
How to install the Software

Add software for the description below.

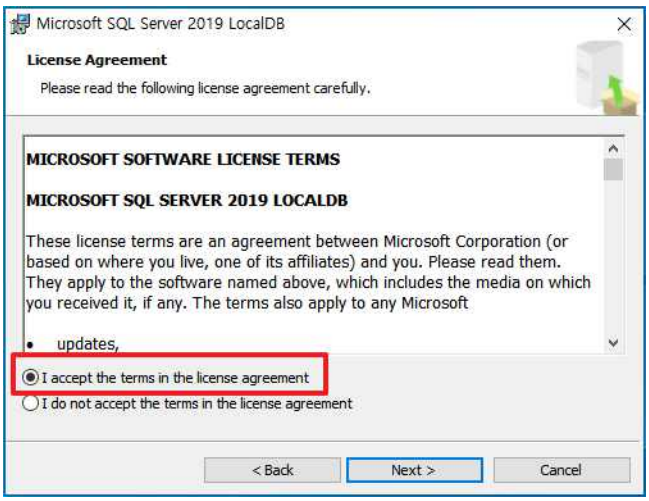
① Close every application before beginning installation.

② Execute "SqlLocalDB.msi" under your CD-ROM drive, download folder or USB memory.

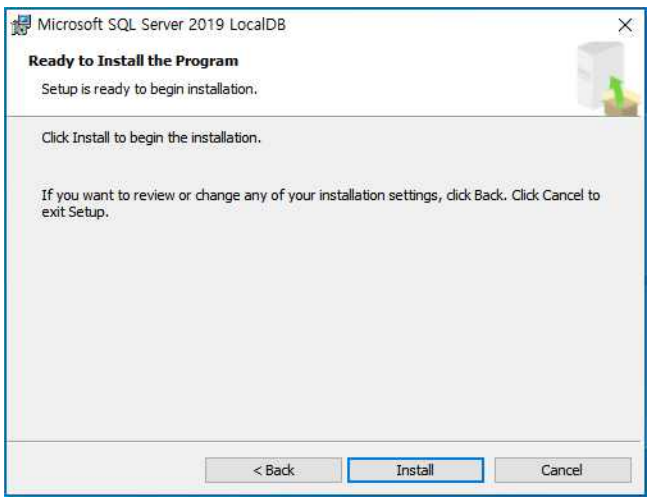
③ Follow each instruction on each step.



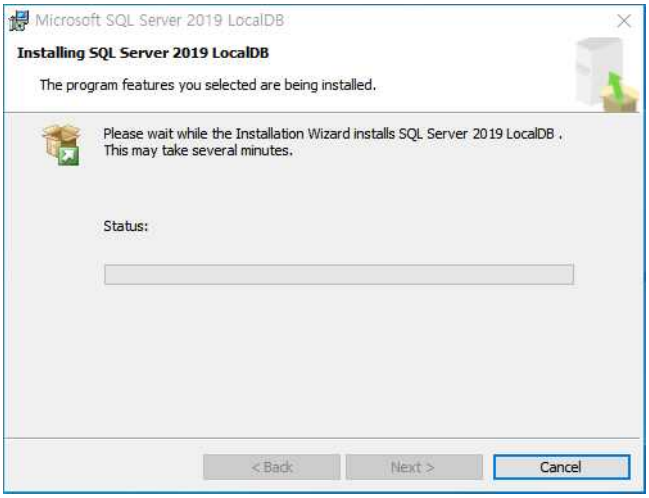
< Step 1>



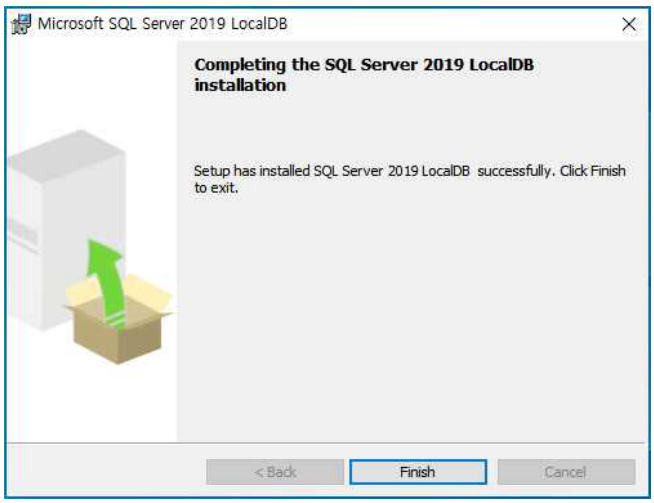
< Step 2 >



<Step 3 >



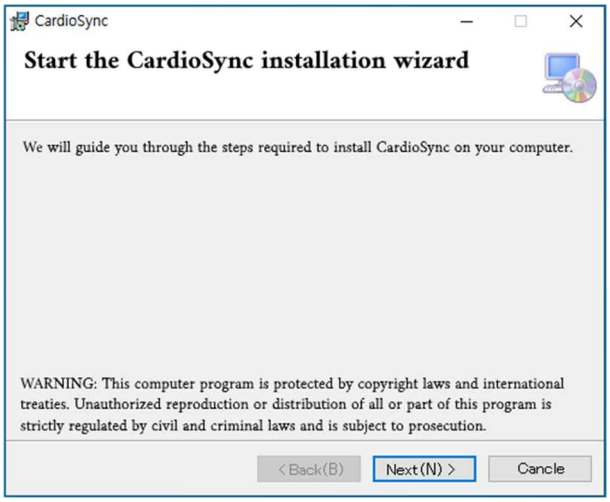
< Step 4 >



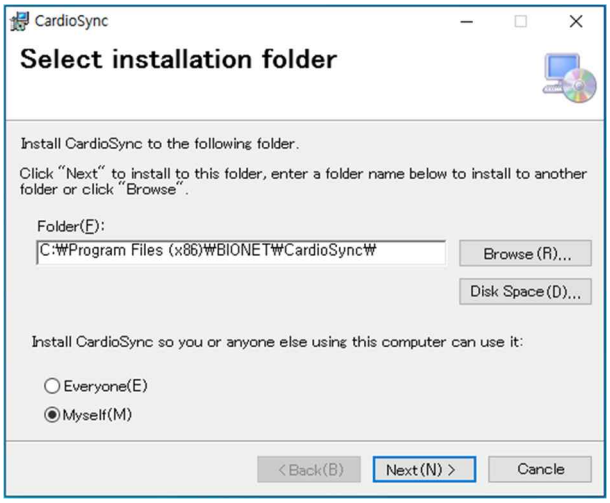
< Step 5 >

④ Execute "setup.exe" or "Cardio P1 ECG_X.XX.XXX_YYYYMMDD.msi" under your CD-ROM drive, download folder or USB memory.

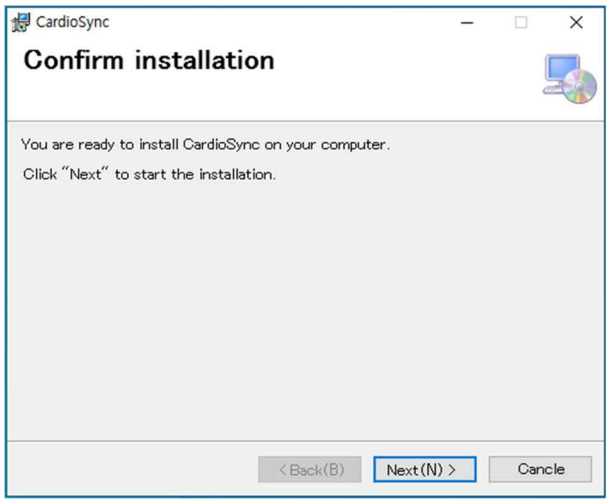
⑤ Follow each instruction on each step.



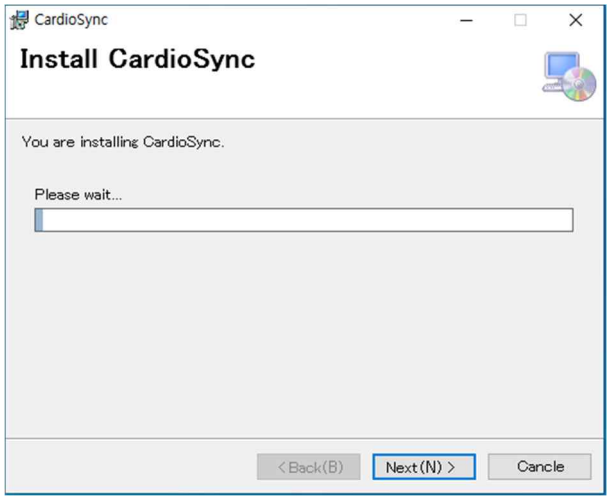
< Step 1 >



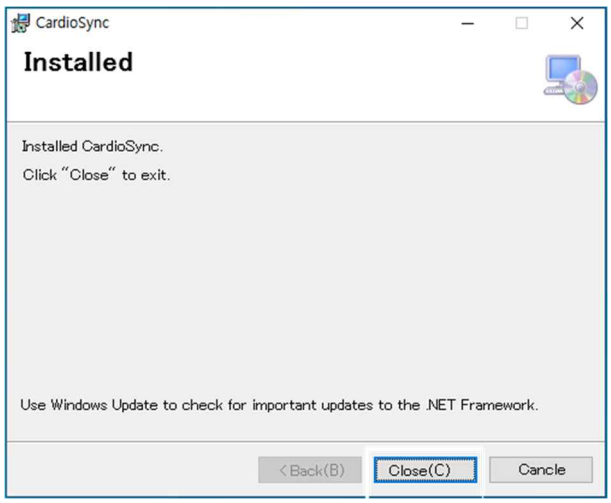
< Step 2 >



< Step 3 >



< Step 4 >



< Step 5 >

Power Connection

Plug the power (USB data) cable into the USB port of the PC and the side connection cord of the Cardio P1 and the device will work.

Patient Cable Connection

- Connect the patient cable to the patient cable connection port located on the bottom of the main unit.
- Make sure to connect limb electrode to the terminals in RL(N), LL(F), RA(R) and LA(L) of the patient and the chest electrode to the terminals in V1(C1), V2(C2), V3(C3), V4(C4), V5(C5) and V6(C6).

Warning
Modifications to this equipment are not allowed. Do not disassemble or modify this equipment without the manufacturer's approval. Repair or disassembly of the equipment can only be performed by those who have product repair qualifications recognized by Bionet. Bionet is not liable for any problems arising from the disassembly and modification of equipment by an unqualified person.

General Precautions

Please be aware of the following guidelines to ensure safe usage of the software

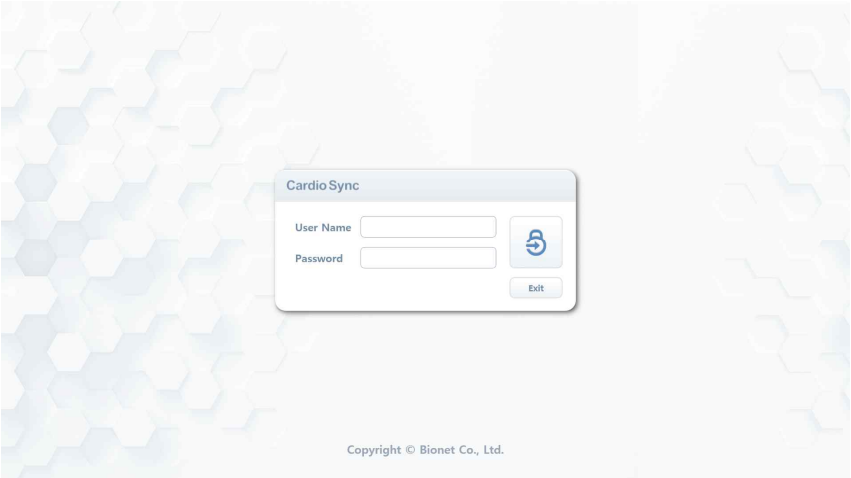
- Use strong passwords: Choose a strong password that includes a mix of uppercase and lowercase letters, numbers, and symbols. Never use the same password for multiple accounts.
- Use antivirus software: Install a reliable antivirus program and run regular scans to keep your computer safe from malware and viruses.
- Backup your data: Regularly backup your important files to an external hard drive or cloud storage to prevent data loss.

Connecting the Network

As only the service technicians can connect this equipment to the network, consult with the IT staff in the hospital in advance.
Follow IEC 80001-1, which is the Risk management of IT networks to which medical devices are connected.

6) System the Start

After everything is ready, run the software and you will see the login screen as shown.



Login

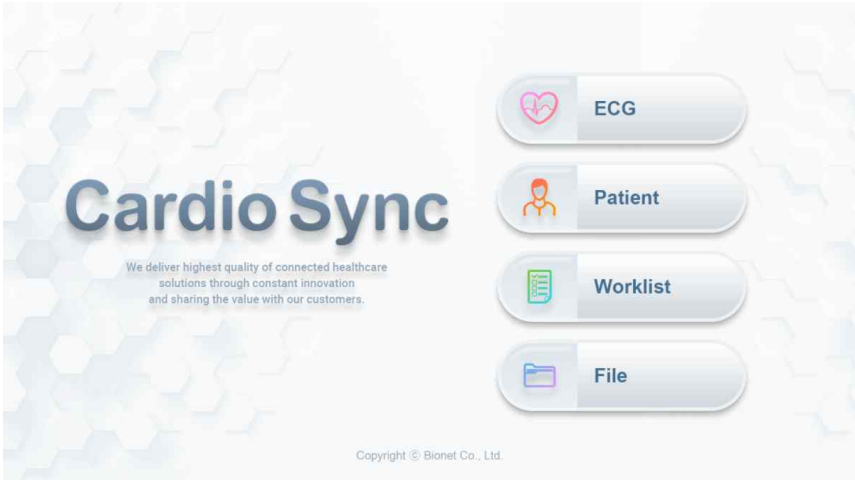
Enter your ID and password.

Roles and privileges are assigned to individual users and may affect each user's scope of access to areas of the workflow and available functions.

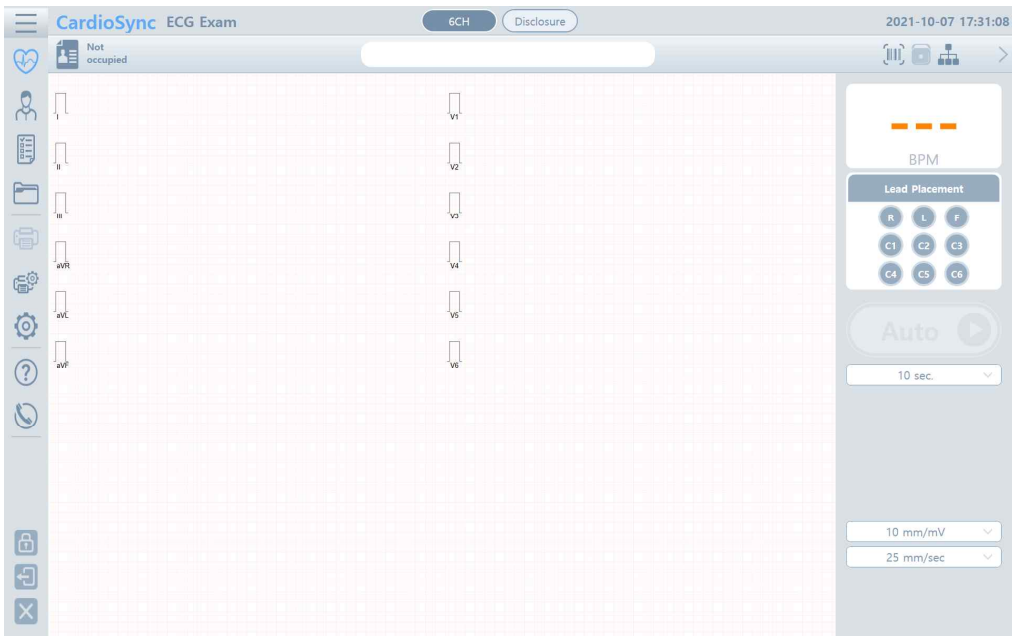
If a function is colored in gray and cannot be entered, it means that the user logged in does not have the privileges to perform the (greyed) task or the task is not available in the current screen.

See "Chapter 2. ECG Recording Preparation – 7) System Setup" for individual users and their privileges.

After login, the menu screen appears as shown below.

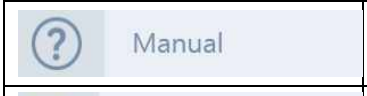
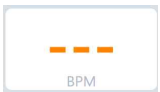


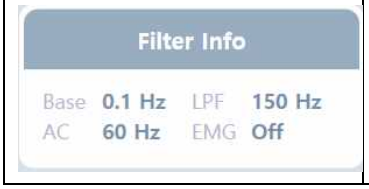
Click the items to inspect on the screen to move to the default screen on the selected menu. The figure below shows the initial ECG screen that moves when the 'ECG' menu is selected.



If you know the following on the ECG initial screen, you can use it more conveniently.

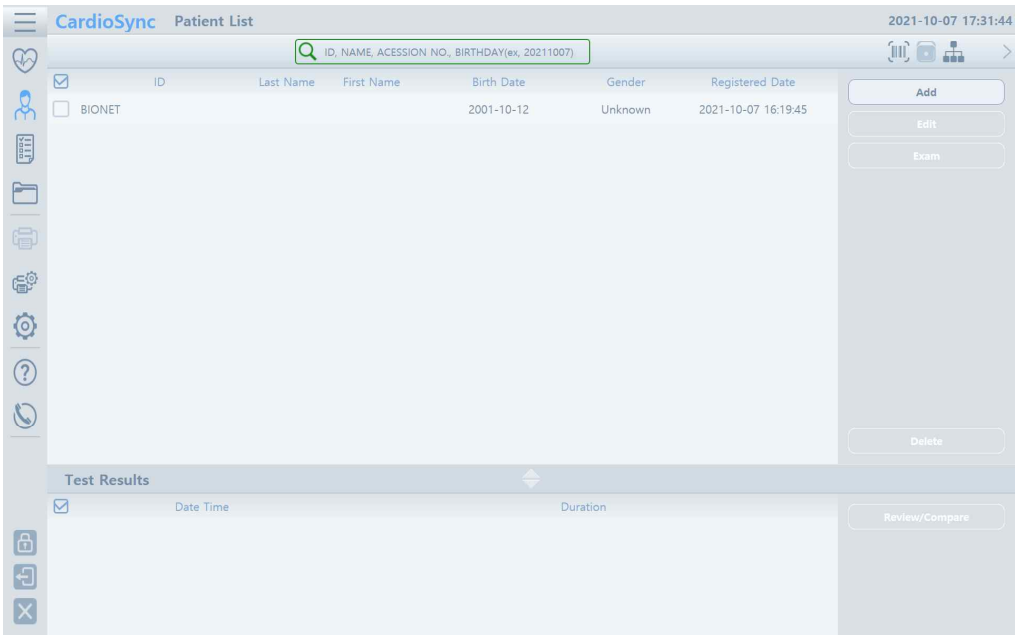
Menu	explanation
Not occupied	Enter patient information or confirm contents
	Real-time diagnosis name display
ECG	ECG screen

	Patient management screen
	Worklist screen
	File screen
	Print execution
	Print setting
	System setting
	Help
	Company information.
	Minimize button
	Fix the screen.
	Log out
	End of the program.
	Setup or indicate recording mode (Displayed as 10s, 1m, 3m, 5m, 10m, 20m, 30m)
	Heart rate display
	Confirm lead fault information
	Auto Button
	Move to the retry queue (error file management while sending to the server) screen
	Indicate the connection of barcode reader

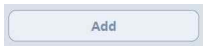
	Indicate Cardio P1 connection
	Indicate or setup network status
	Indicate or setup the current date or time
	Indicate or setup the print speed
	Indicate or setup the signal size
	Set filter value display window

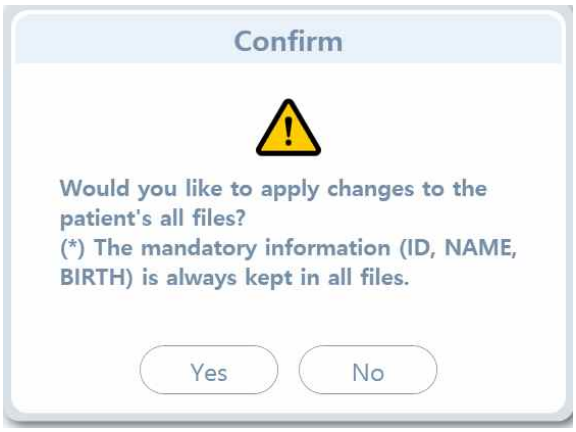
Note
Function keys available in Cardio P1 - F9 Button : Auto - F10 Button : Save - F11 Button : Export - F12 Button : Print

The following is the patient examination data management screen that moves when the 'Patient List' menu is selected.

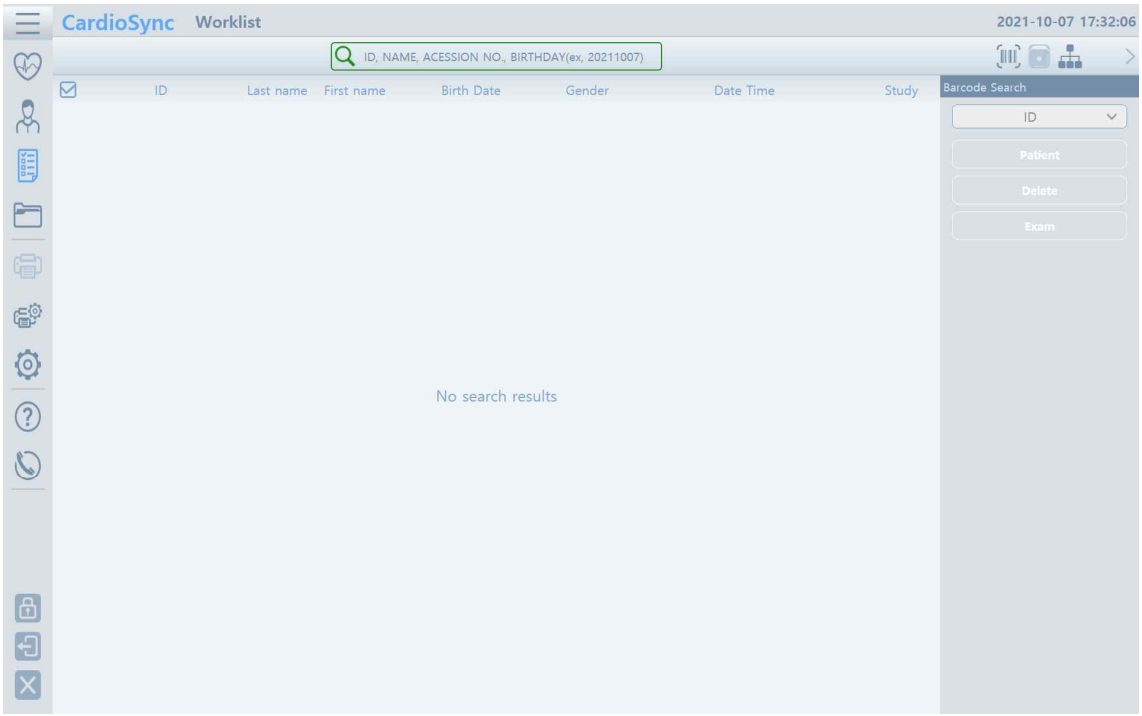


Followings are recommended to know on the exam request data managing screen for more convenient usage.

Menu	Explanation
	Search for data by entering search conditions
	Move to the exam screen
	Add patient information
	Edit patient information
	Delete patient information
	Check measurement information / Compare two measurement values

Note
Applicable matters when editing patient information. - Basic Item (ID, Name, Birth) : DB, All files - Additional items (ETC.) : DB, User decides whether to apply to all files 

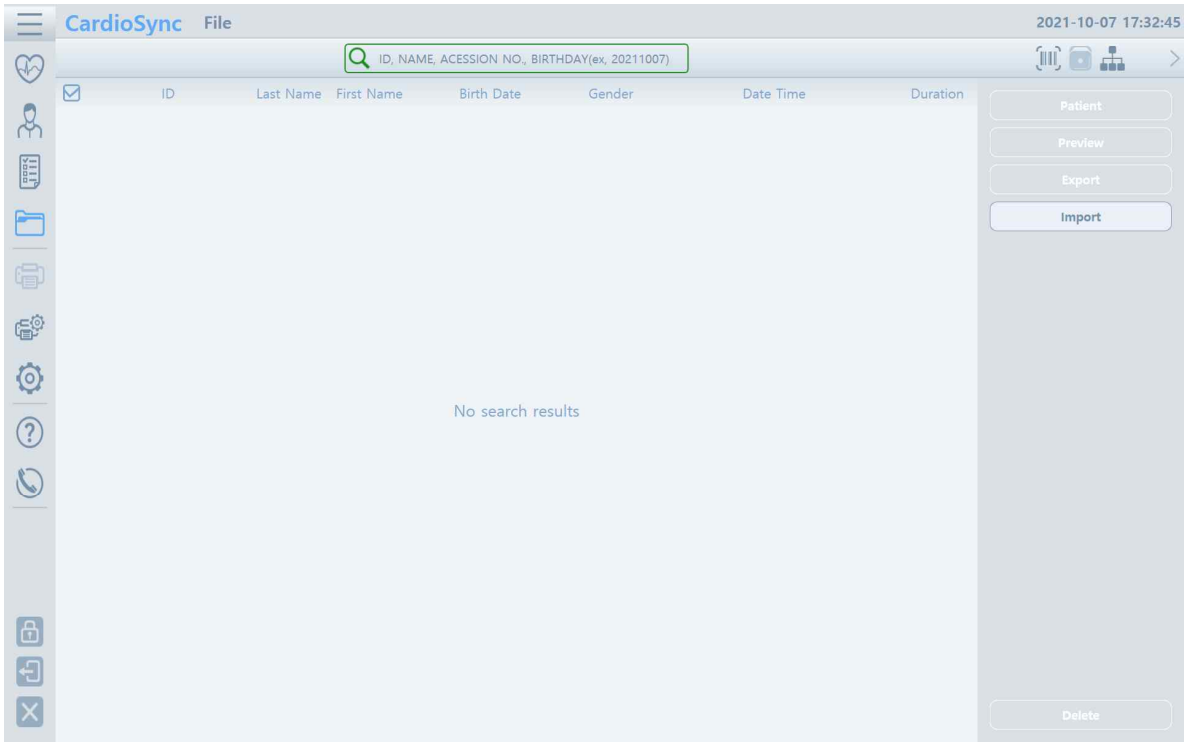
Following is the ECG data file managing screen when selecting 'Worklist' menu.



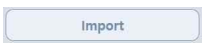
Followings are recommended to know on the data file managing screen for more convenient usage.

Menu	Explanation
ID, NAME, BIRTHDAY	Search for data after entering searching conditions
Exam	Move to the exam screen
Update	Get Worklist Menu button that appears when PACS or GDT is connected
ID	Search condition setting
Patient	Check patient information

Following is the ECG data file managing screen when selecting 'File' menu.

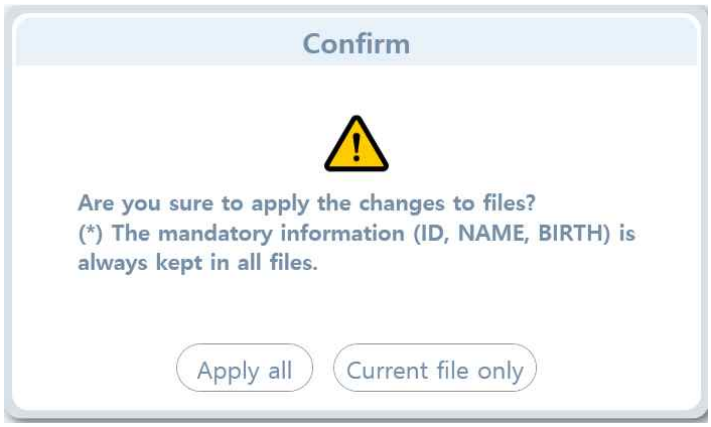


Followings are recommended to know on the data file managing screen for more convenient usage.

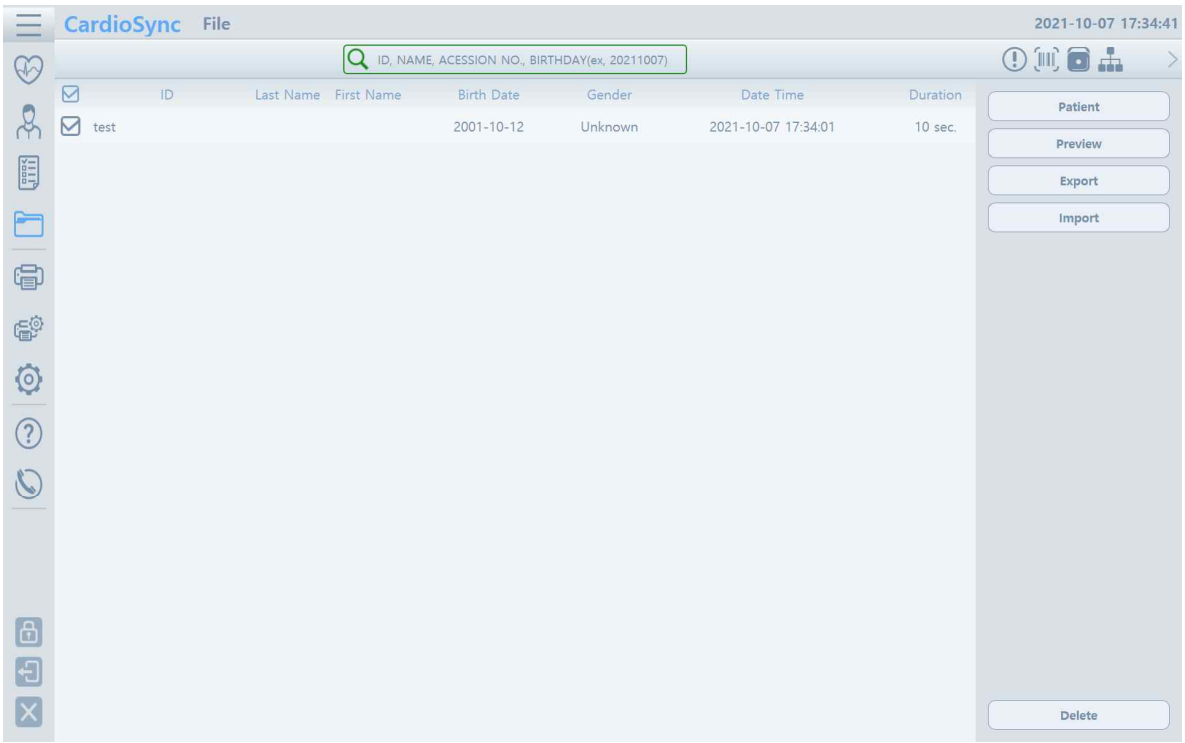
Menu	Explanation
	Search for data after entering searching conditions
	File export
	File import
	File preview
	Check patient information

Note
Applicable matters when editing patient information. - Basic Item (ID, Name, Birth) : DB, All files - Additional Item (ETC.) : DB, User decides whether to apply to all files or the current

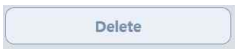
file



The following is the Retry Queue data management screen that moves when (Retry Queue icon) is selected. The Retry Queue manages error data when an error occurs during transmission to the server.

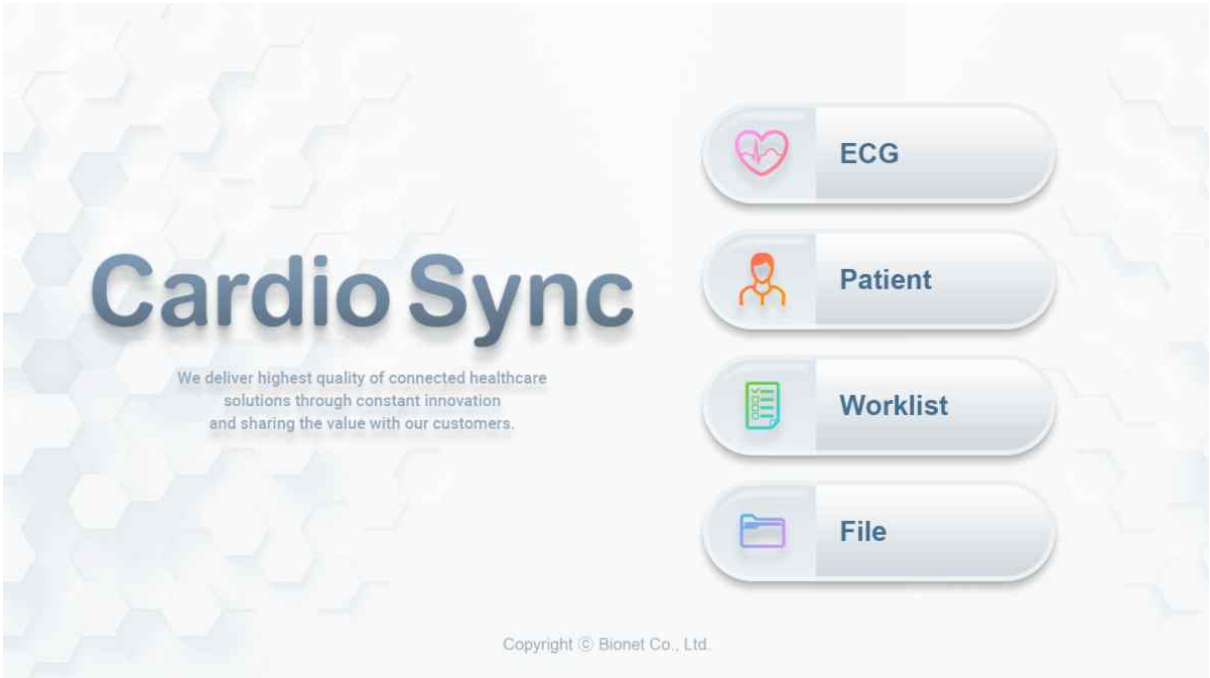


Followings are recommended to know on the Retry Queue managing screen for more convenient usage.

Menu	Explanation
	Send selected data
	Delete selected data

Note
-  icon is indicated on the right top corner only if there is an error while sending files.

Part I. Using ECG



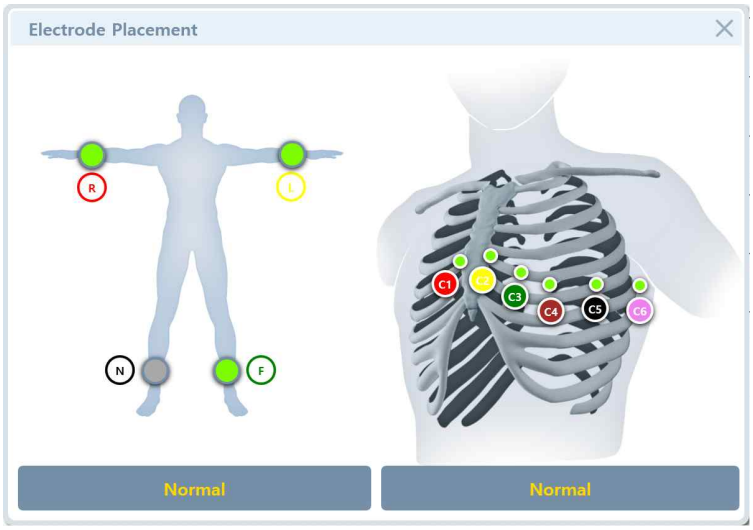
Chapter 2. ECG Recording Preparation

1) Attaching the Electrodes

When you touch 

(Lead Fault Information) located in the center of the menu bar at the top of the ECG Main screen, a picture showing where to attach the electrodes is displayed.

To record a standard 12-lead ECG, attach electrodes to the patient's body as shown below.



The positions to attach limb electrodes are as follows:

- RL (N): Right leg
- LL (F): Left leg
- RA (R): Right arm
- LA (L): Left arm

The positions to attach the chest electrodes are as follows:

- V1 (C1): Boundary of fourth intercostal on right side of chest
- V2 (C2): Boundary of fourth intercostal on the left side of chest
- V3 (C3): Mid-location between V2(C2) and V4 (C4)
- V4 (C4): Mid-location of the front side of fifth intercostal collarbone
- V5 (C5): Front armpit on the horizontal line with V4(C4)
- V6 (C6): Mid-armpit on the horizontal line with V4(C4), V5(C5)

2) Connecting Electrodes

*** Checklist**

- Before the exam, check the condition of the equipment and patient, and whether each electrode is well attached.
- Make sure that there are no mechanical hazards.
- Check the status of cables and accessories connected externally.
- Check the status all the measuring devices for the patients

Connecting Patient Cable

Connect the patient cable to the port on the right side of body and connect limb electrodes to the terminals of RL (N), LL (F), RA (R), and LA (L) of patient cable connected in the Cardio P1 and chest electrodes to the terminals V1 (C1), V2 (C2), V3 (C3), V4 (C4), V5 (C5) and V6 (C6).

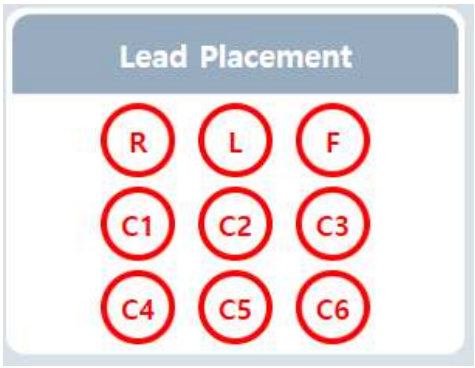
How to Attach the Electrodes

Have the patient lie down on the bed and release the tension in the skin area where the electrodes will be attached. Clean the area with disinfected alcohol or water before attaching electrodes. In case the patient is hairy on the attaching spots, shave them. If the attachment body part is curved and it is difficult to attach the electrodes, attach them to the positions that are as similar as possible without a curve.
If the noise is severe even if you have used alcohol or water, apply the ECG gel to the attaching spots before attaching the electrodes.
Be sure to wipe off the used ECG Gel, because if it gets dried and hardened, it can generate noise in the ECG signal.

Warning
Be sure to use only the electrodes and patient cable provided by Bionet. Bionet is not liable for any problems caused by your using unauthorized parts.

What to Do with Poor Lead Connection

Turn on the equipment, enter the ECG mode, and check the connection of all leads and the noise level of the waveform. A message appears in case of a lead fault.



Note
- Lead fault message appears only when Lead fault is set to On in ECG General Setup. Otherwise, it will not appear. - Fault leads are shown in red and saturation leads in yellow. - Proceed with the ECG exam only when the leads are connected properly.

Take the following measures when the lead connection is poor.

- When the electrodes come off from the skin: Reattach the electrodes following the electrode attachment method.
- When conductivity between the skin and the electrodes is weak: Apply the ECG gel to the electrode-attaching spots and reattach the electrodes.

If the ECG signal is not accurately acquired even after you try all the solutions above, the patient cable may be non-conforming. Contact Bionet's service center.

3) Recording ECG

- Enter accurate patient information.
- Connect the ECG cable to the patient in compliance with the ECG measurement preparations.
- Check or change settings such as Filter, Gain, Output Speed, Channel Configuration, Rhythm, etc.
- Refer to What to Do with Poor Lead Connection if the waveform drawn in the LCD screen is

abnormal or there is too much noise.

- If the waveform displayed on the LCD screen is normal, press the [AUTO] key to record the ECG.
- Press the [STOP] key to stop printing or saving the ECG results.

4) Basic Setup

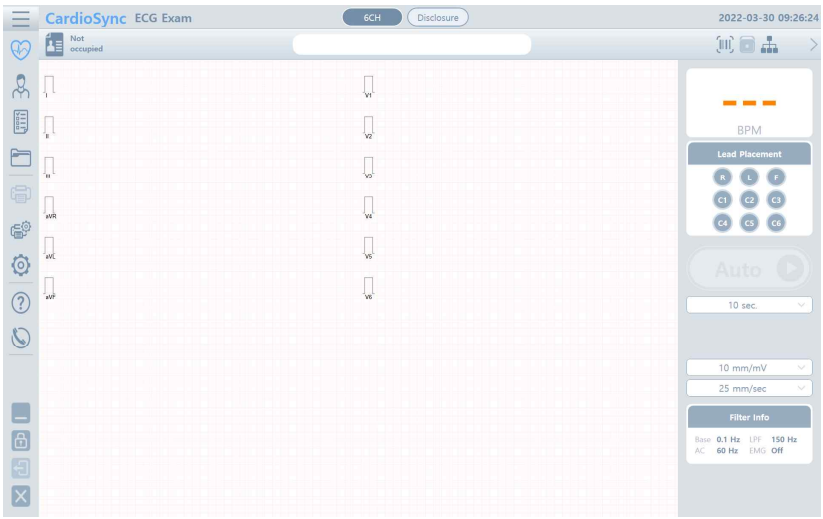
General Information

When you turn on the equipment, top and bottom menu bars and graphic window appear on the LCD screen.

Top menu bar: Patient Information, Test Mode, Heart Rate, Lead Fault, External Device Connection Status, Network Status, Power Status, Current Date and Time

Bottom menu bar: Output Speed, Gain, Filter, Print Form, Disclosure, and Setup.

Touch the menu buttons on the LCD screen to change settings.



Setting Values Using Touch Screen

- Selecting Menu

  Touch the menu buttons on the screen.

- Setting the Value

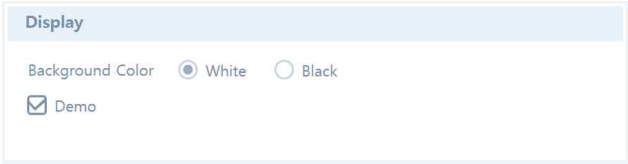
  Select a menu and touch [OK].

Screen Output

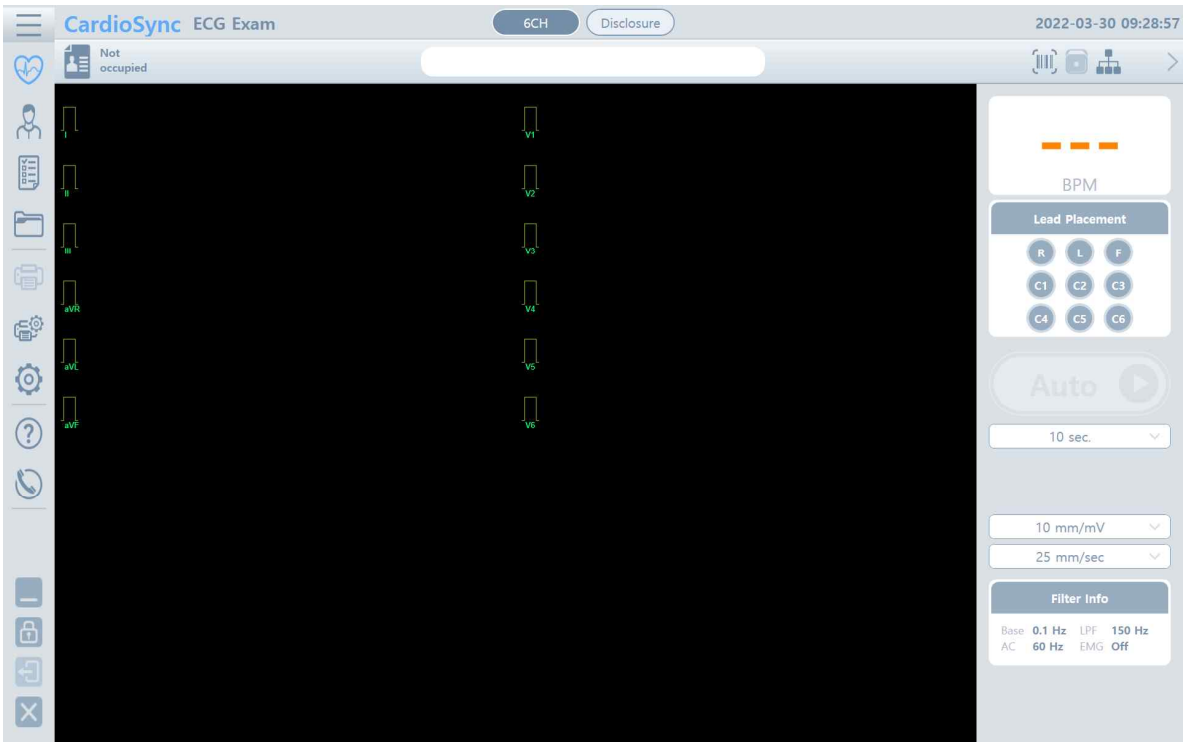
The current ECG signal is drawn on the LCD screen in real-time.

Start the test after confirming that the signal is correctly transmitted from all leads.

The screen output background color of the ECG waveform can be selected from either white or black and can be changed in the Setup → ECG → Display → Background menu.



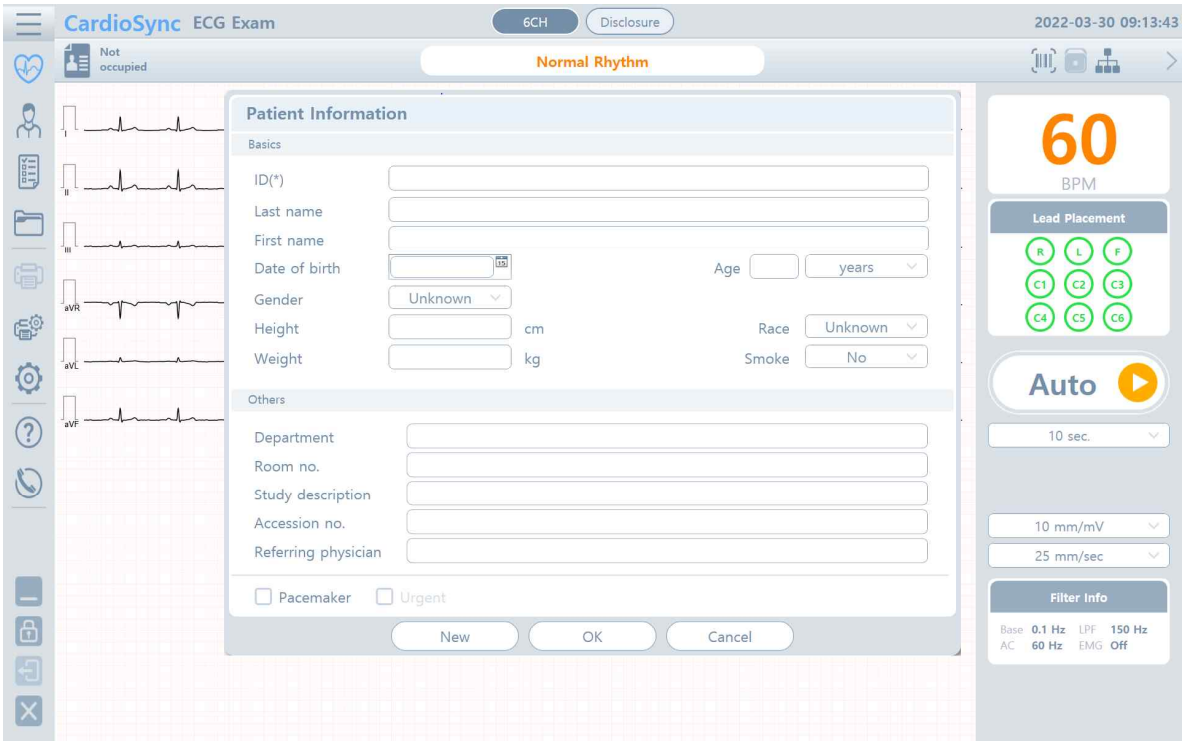
In the black background, the waveform is drawn without a grid as shown below.



Patient Information

Fields marked with * are required inputs.

Automatic diagnosis is made based on the ECG recording for 10 seconds and is available for pediatrics and adults. It is carried out according to the age of the patient.



Patient ID

Enter a unique number used in the hospital to classify patient medical data. Touch the input field of ID to display the keypad window consisting of alphabets and numbers, and use it to enter patient ID.

Note
- You cannot use ., ", <, >, ?, /, *, |, :, ₩ & characters for ID. - Use only plain alphabets and numbers for ID. If you enter an ID in Latin extended characters or Russian, an error may occur when you transfer files with the IDs to a PC or USB memory.

Patient Name

Enter the patient name in the same way as entering the ID.

Date of Birth

Touch the input field of Date of Birth to calendar-type date input window as shown below appears. Enter the patient's date of birth. Patient's age is automatically calculated and entered.

Age

Enter the patient's age directly.

Enter the age of pediatrics or adults. Enter the age in weeks or days if you cannot enter the age in years.

Note
- Age is automatically calculated when the date of birth is entered. - If age is not entered, an adult diagnosis is provided.

Gender

Touch the input field of Gender to select Male or Female.

Height

Enter the patient height in the same way as entering the age.

If the Height Unit is set to inches in System General Setup, enter the height in ft and inches.

Weight

Enter the patient weight in the same way as entering the age.

Race

Enter the race of the patient. There are 3 registered races: Asian, White, and Black.

Touch the input field of Race to select the race type.

Smoke

Mark whether the patient is smoking.

Urgent

Mark whether the patient needs urgent care.

Pacemaker

Set whether to display the pacemaker position on the RHYTHM or on the diagnosis when a pacemaker signal is detected.
When set to On, pacemaker position is specified; Otherwise, it is not.

Note
- In general, 'pacemaker' items are set to be 'Off.' Only if it is the patient using pacemaker, it is recommended to set it as 'On.' - In case of lead fault, pacemaker signal might not be detected.

Others

Enter Department, Room No., Study Description, Accession No., Referring Physician in the same way as entering the ID. Set Urgent to Yes for urgent patients and Pacemaker to Yes for pacemaker patients.

Touch [OK] to save the settings or [Cancel] to cancel the settings. Touch [New] to initialize all the patient information you have entered.

Using a Barcode Reader

Place the cursor on each item in the patient information screen and scan the barcode. Information is entered automatically.
When you scan the barcode in the ECG main screen, the patient ID is entered automatically.

Basically, you can use any kind of barcode reader.
However, since the default setting of the entry method of each product may be different, check the method supported by Bionet before using them.

- Entry methods supported by Bionet products: International standard and USB
- The products that have been tested by connecting to Bionet equipment are listed below.

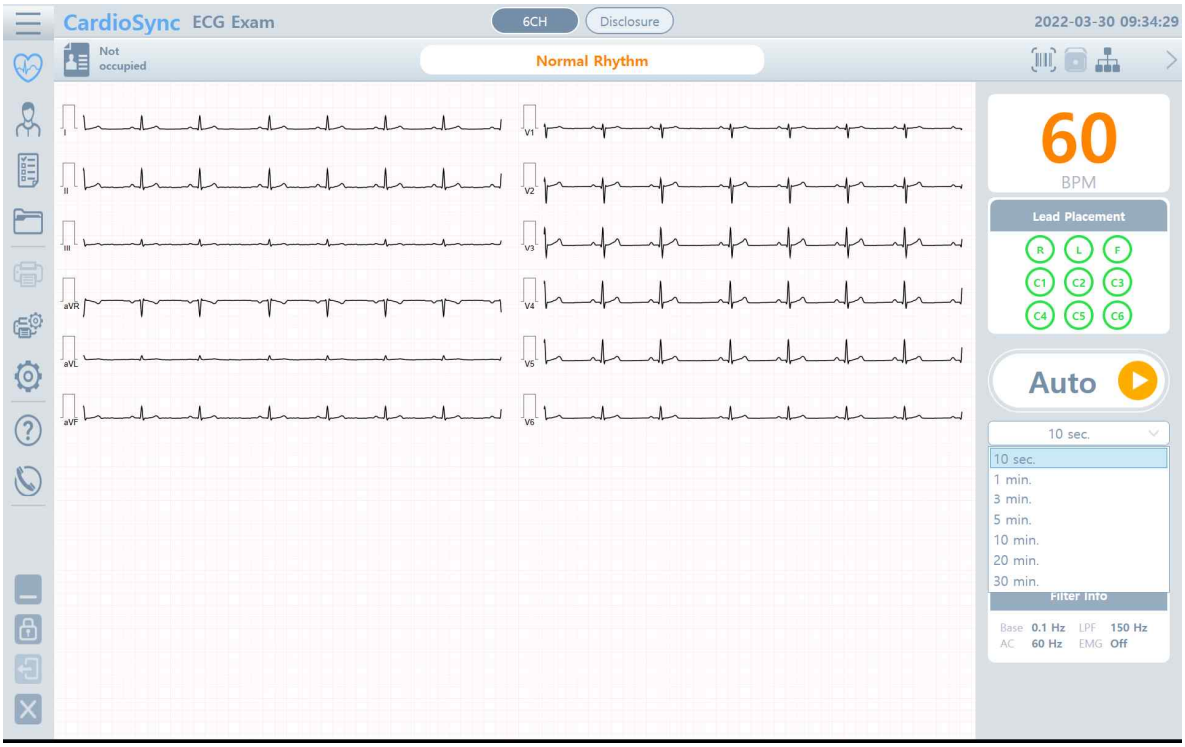
N0.	Manufacturer	Product name	Product Image
1	Symbol	LS-2208	
2	ZEBEX	Z-3110	
3	Honeywell	MS5145	
4	Honeywell	DS2208	

Note
Each barcode reader has a product-specific initialization code. Be sure to read the user manual of the product and check the entry method before initializing it.

Measurement Time Setting

The measurement time setting is used when you want to perform a 10-second recording measurement or output 1CH for a long time.

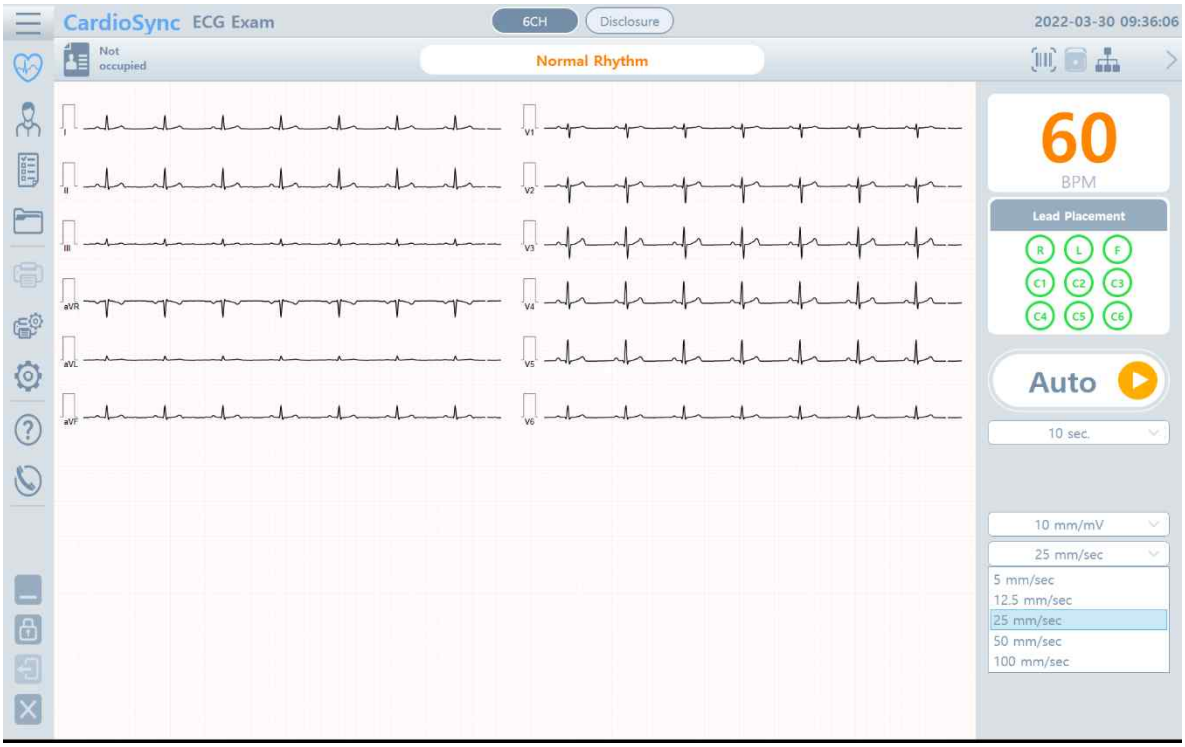
It can be set to 1, 3, 5, 10, 20, or 30 minutes, and at this time, it is output with the set lead.



Note
Real-time diagnosis is issued by referring to the leads of the Long-term ECG. Set Lead II because it is the largest in general, however, if its waveform is not large enough, choose another lead with the largest and best waveform.

Output Speed

Adjust the width of the output signal for screen output and printout. The available values are 5mm/sec, 12.5 mm/sec, 25mm/sec, 50mm/sec, and 100mm/sec. 25mm/sec means that the ECG signal for 1 second is recorded with a length of 25mm.



Note
- When you set the recording mode to 3, 5, 10, 20 and 30min, the signal is always printed at 12.5mm/sec.

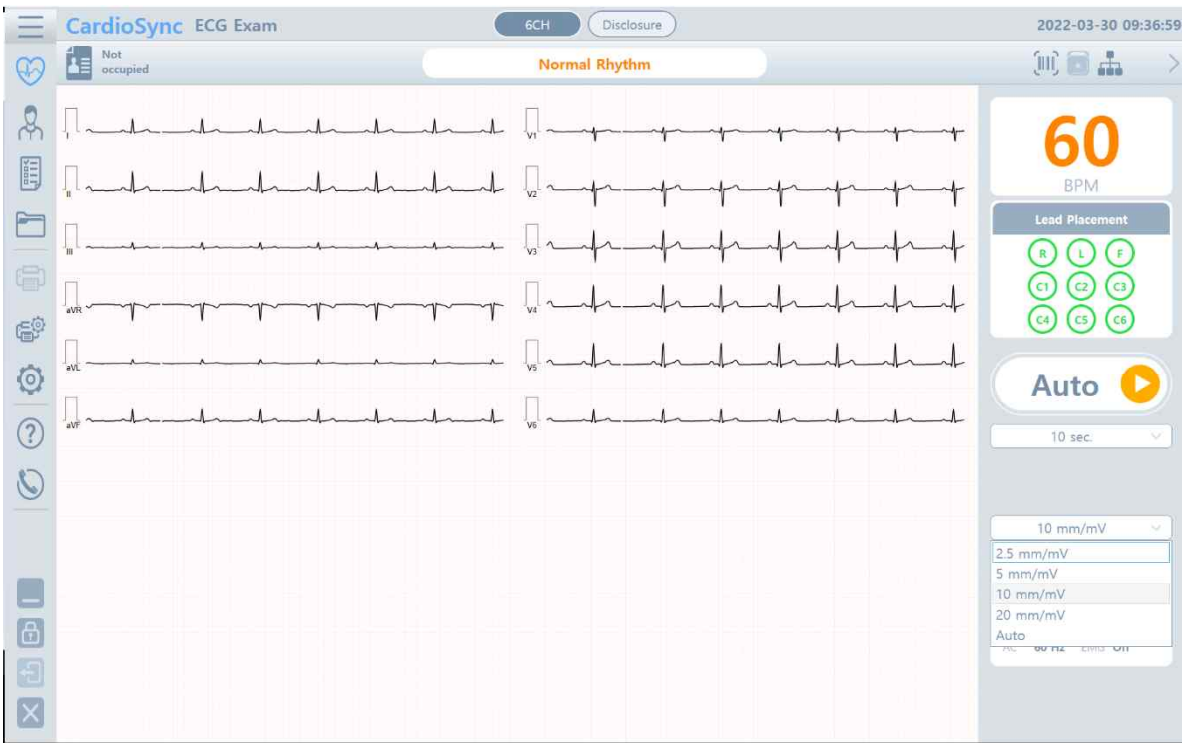
Setup Signal Scale

If the scale of output signal is too high and is duplicated with signals in neighboring channel, or if the scale of output signal is too low making it difficult to decipher, this function is used to adjust the signal scale.

There are five auto setups function that all the 12 leads are setup to 2.5mm/mV, 5mm/mV, 10mm/mV and 20mm/mV, limb lead (I, II, III, aVR, aVL, aVF) is setup to 10mm/mV and chest lead (V1, V2, V3, V4, V5 and V6) is setup to 5mm/mV.

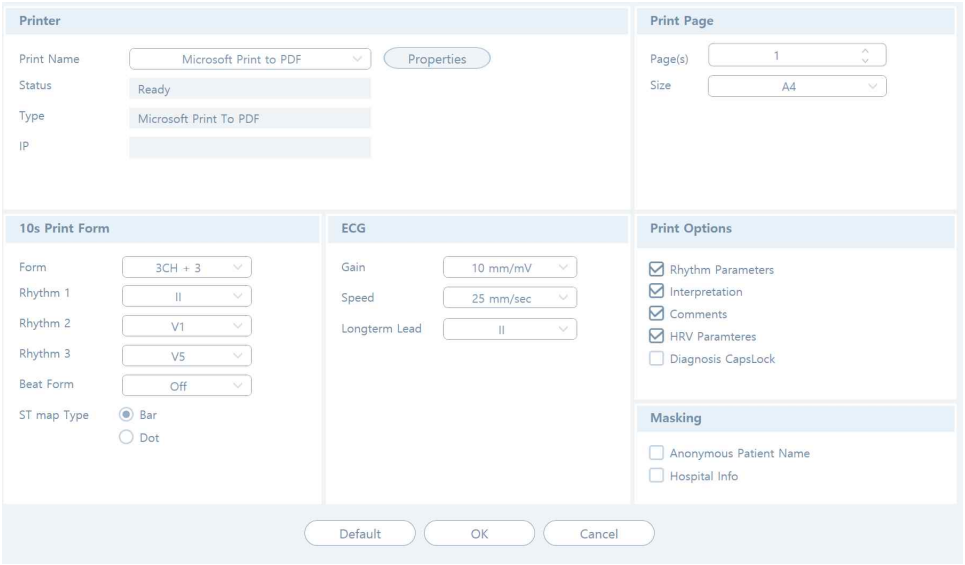
10mm/mV means to output the signal in 1mV in the size of 10mm.

Since the signal scale is indicted with the names of each channel on the left side of graphic window, it is possible to conveniently confirm the modified information.



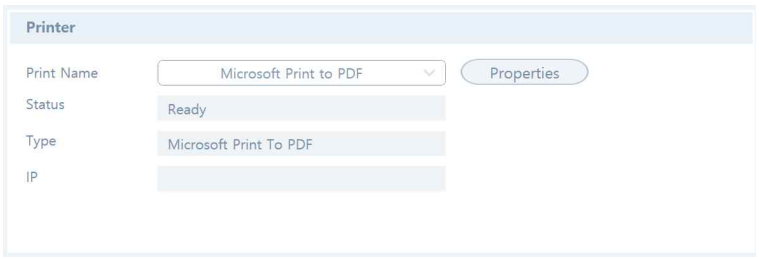
Note
- On the output of recording mode in the setup of 10sec, the preview gain window can modify - On the output of recording mode in the setup of 1min, the preview gain window cannot be modified, output with preset gain. - On the output of recording mode in the setup of 3, 5, 10, 20 and 30min, the preview gain window cannot be modified, and the output is fixed at 5.0mm/mV.

Setup Print



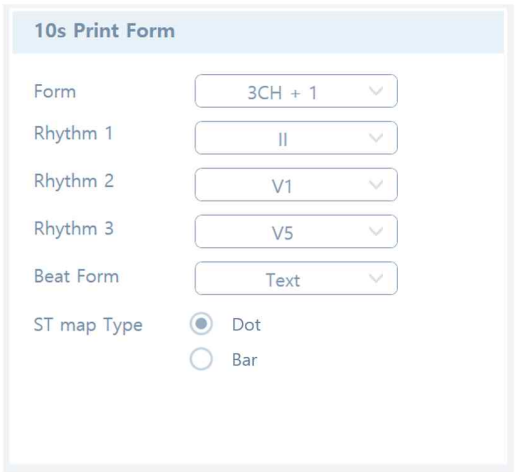
Printer

Setup the printer to print. If you click the Properties button, you can use the normal Windows printer settings.



10s Print Form

Set the diagnosis print format.



Form

Output form	Explanation
3CH+3	10-second resting ECG recording: I, II, and III in the first 2.5 seconds; aVR, aVL, and aVF in the next 2.5 second; V1, V2, and V3 in the next 2.5 seconds; and V4, V5, and V6 in the next 2.5 seconds. The 3-lead rhythm is recorded at the bottom for 10 seconds.
3CH+1	10-second resting ECG recording: I, II, and III in the first 2.5 seconds; aVR, aVL, and aVF in the next 2.5 second; V1, V2, and V3 in the next 2.5 seconds; and V4, V5, and V6 in the next 2.5 seconds. The 1 lead-rhythm is recorded at the bottom for 10 seconds.
6CH+1	10-second resting ECG recording: I, II, III, aVR, aVL, and aVF in the first 5 seconds; V1, V2, V3, V4, V5, and V6 in the next 5 seconds. The 1 lead-rhythm is recorded at the bottom for 10 seconds.
12CH	The 12-lead rhythm is recorded simultaneously for 10 seconds in the order of I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6.
6CH+1(ST)	8-second ECG recording: I, II, III, aVR, aVL, and aVF in the first 4 seconds; V1, V2, V3, V4, V5, and V6 in the next 4 seconds with ST Map displayed on the right. The 1 lead-rhythm is recorded at the bottom for 10 seconds.

Rhythm Channel (Rhythm CH1, Rhythm CH2, Rhythm CH3)

Set the rhythm-representative lead used in the 3CH+3, 3CH+1, 6CH+1 form for diagnosis printout. The 3CH+3 setting uses all 3 selected values, and only the first value is used for the 3CH+1 and 6CH+1 settings.

By default, it is set to II, V1, and V5. As for 3CH+1, 6CH+1, II is used. All II, V1, and V5 are all used for 3CH+3.

Beat Form

Select between Text, Guide, and Vector as additional print form after a diagnosis is printed. Printing speed is fixed at 50mm/sec regardless of the Output Speed setting.

Output form	Explanation
Text	A representative beat and each diagnostic parameters are printed.
Guide	The representative beat and each diagnostic parameter are printed, along with a diagnostic guide for arrhythmia.
Vector	The representative beat and each diagnostic parameters are printed, marking QRS Vector with an arrow.

ST Map	It outputs the representative bit and each diagnostic parameter and outputs the ST map.

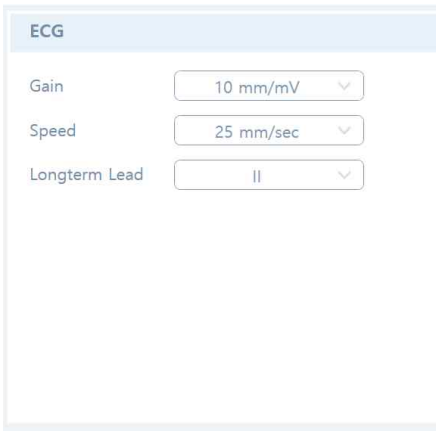
ST Map Type

When selecting the bit form as ST Map, you can select the style of drawing the ST Map.

Output form	Explanation
ST Map (B)	The representative beat and each diagnostic parameters are printed, drawing ST map in the form of Bar.
ST Map (D)	The representative beat and each diagnostic parameters are printed, drawing ST map in the form of Dot.

ECG

Setup recording output form.



Signal Scale Setup (Gain)

Please refer to 'signal scale setup' explained earlier in this manual.

Output Speed Setup (Speed)

Please refer to 'output speed setup' explained earlier in the manual.

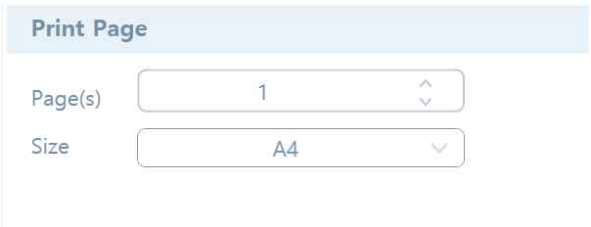
Long Term Lead Setup

Long Term ECG recording is used when preferring to output 1CH for a long time.
It is available to setup and output 1, 3, 5, or 10 minutes. At this time, setup the lead to output.

Note
Real-time diagnosis is based on the lead of the Long Term ECG. Normally, the lead II is the largest, so you can set the lead II, but if the waveform is small, select the other lead with the largest and best waveform.

Print Page

Settings related to the printout



Page(s)

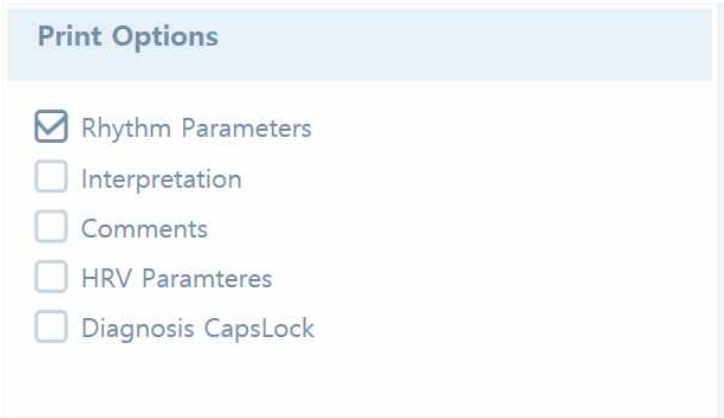
Set the number of prints. Up to 50 sheets

Size

Set the size of the prints

Print Option

Select the option to use when printing.



Rhythm parameters

Select whether to output rhythm parameters when outputting records.

Interpretation

Select whether or not to output diagnostics when outputting records.

Comments

Select whether to output the observations added to the record results.

HRV parameters

Select whether to output HRV parameters when outputting records.

Diagnosis Caps Lock

When outputting a record, the diagnosis name is output in uppercase.

Masking

Set to de-identify patient information when printing.

Anonymous Patient Name

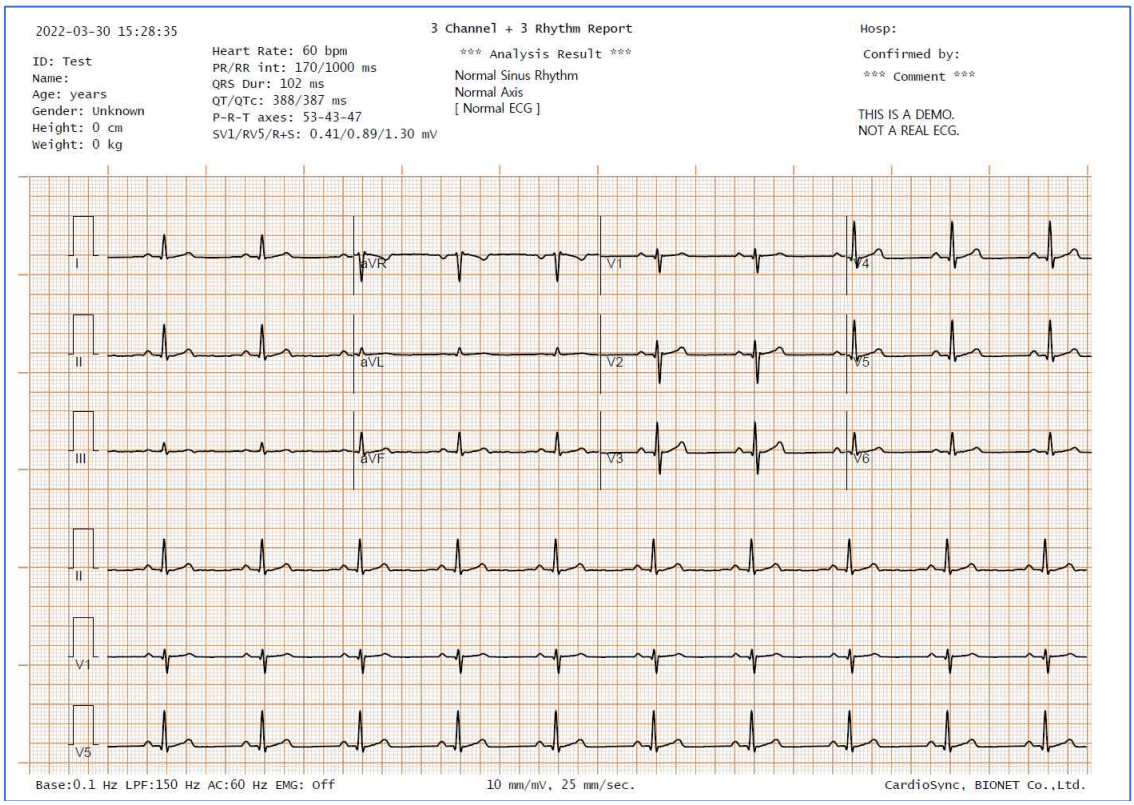
The patient's name is de-identified and hidden and printed.

Hospital Info

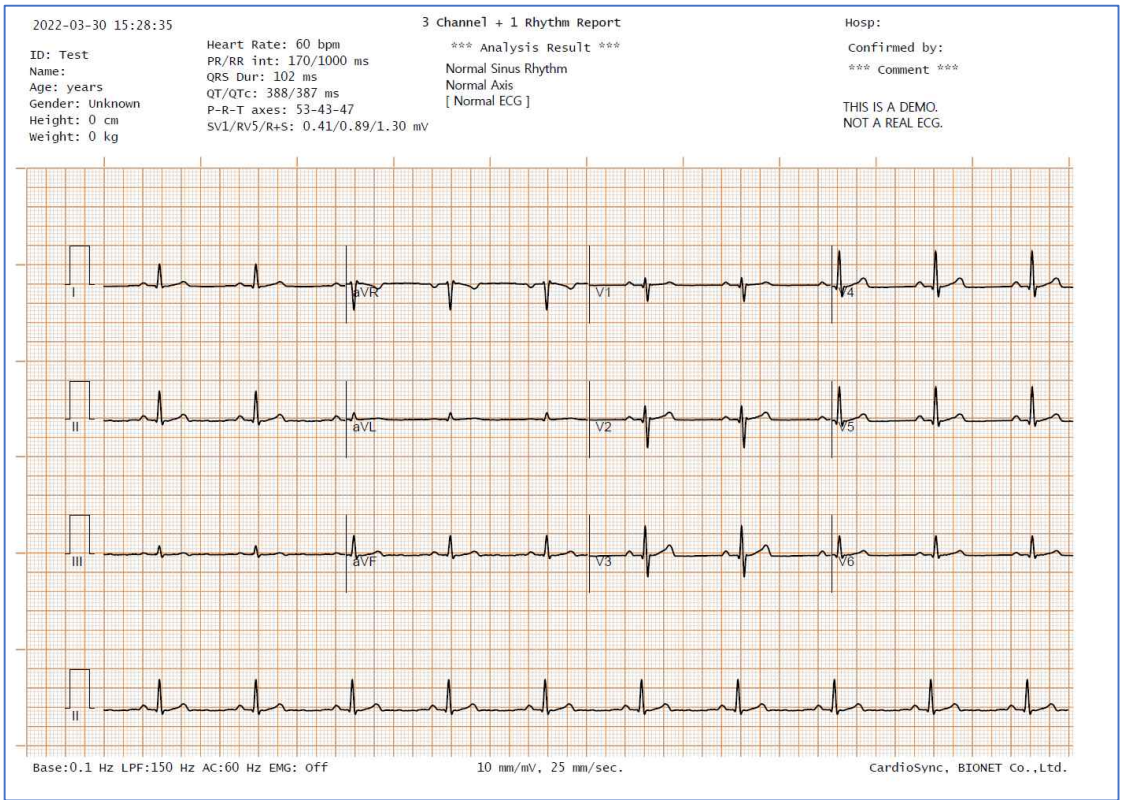
Hospital information is de-identified, hidden and printed.

The followings are examples of print formats:

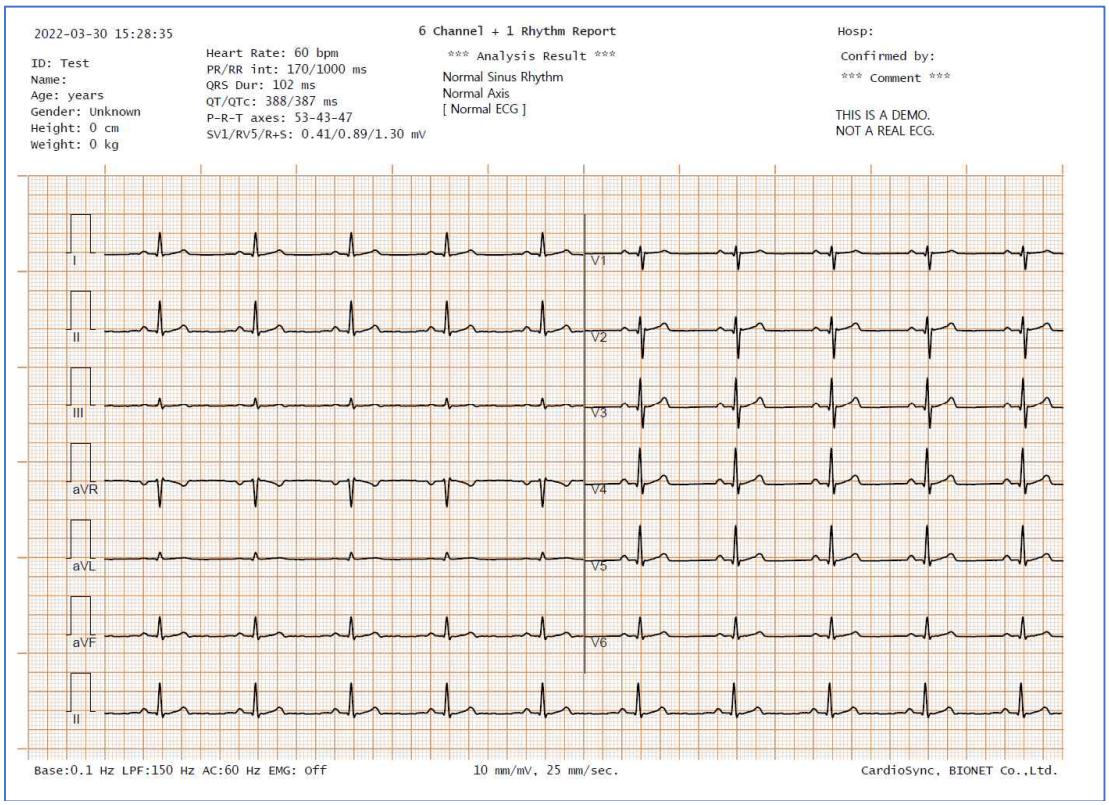
Diagnosis Print Format (3CH + 3RHY)



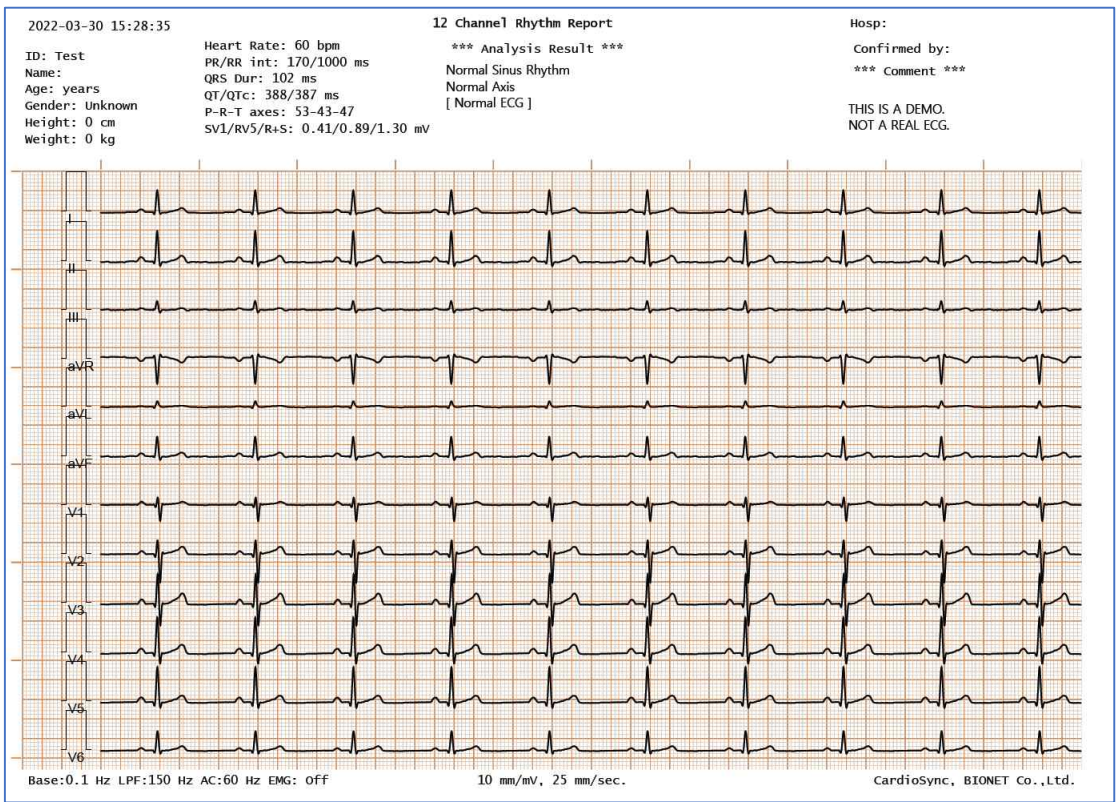
Diagnosis Print Format (3CH + 1RHY)



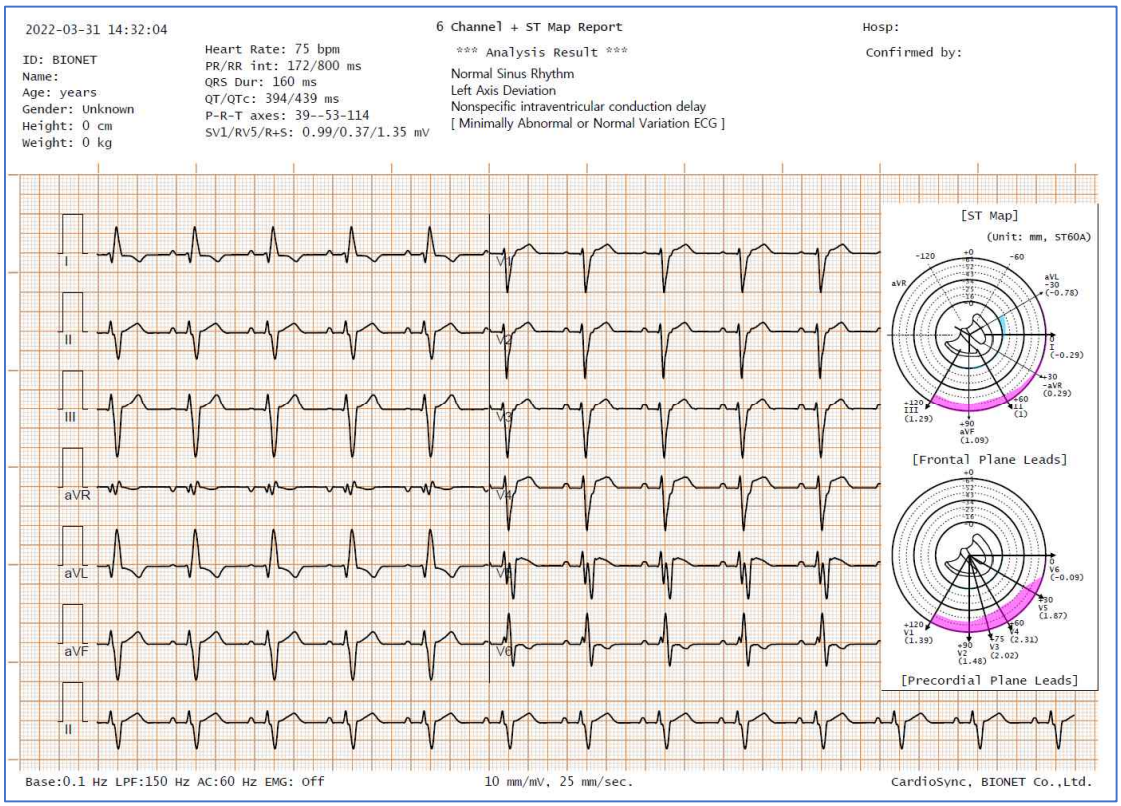
Diagnosis Print Format (6CH + 1RHY)



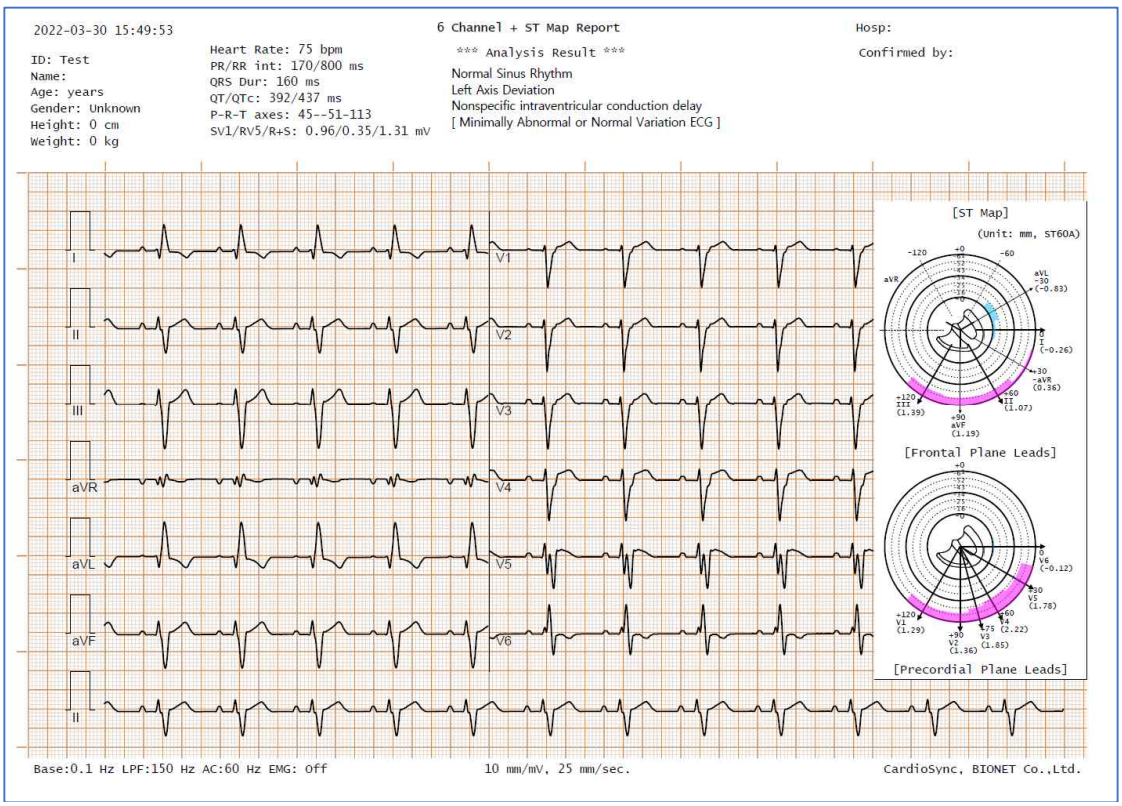
Diagnosis Print Format (12CH)



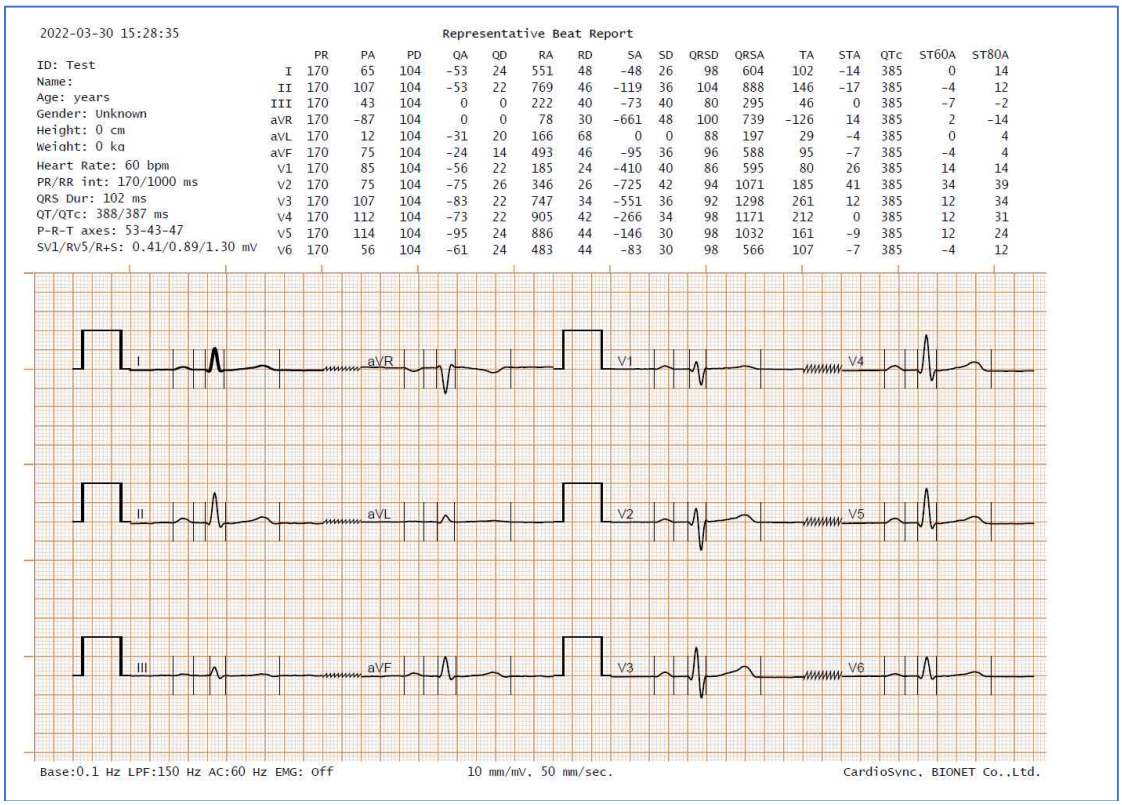
Diagnosis Output Form (6CH+1(ST)-Dot)



Diagnosis Print Format (6CH+1 (ST))

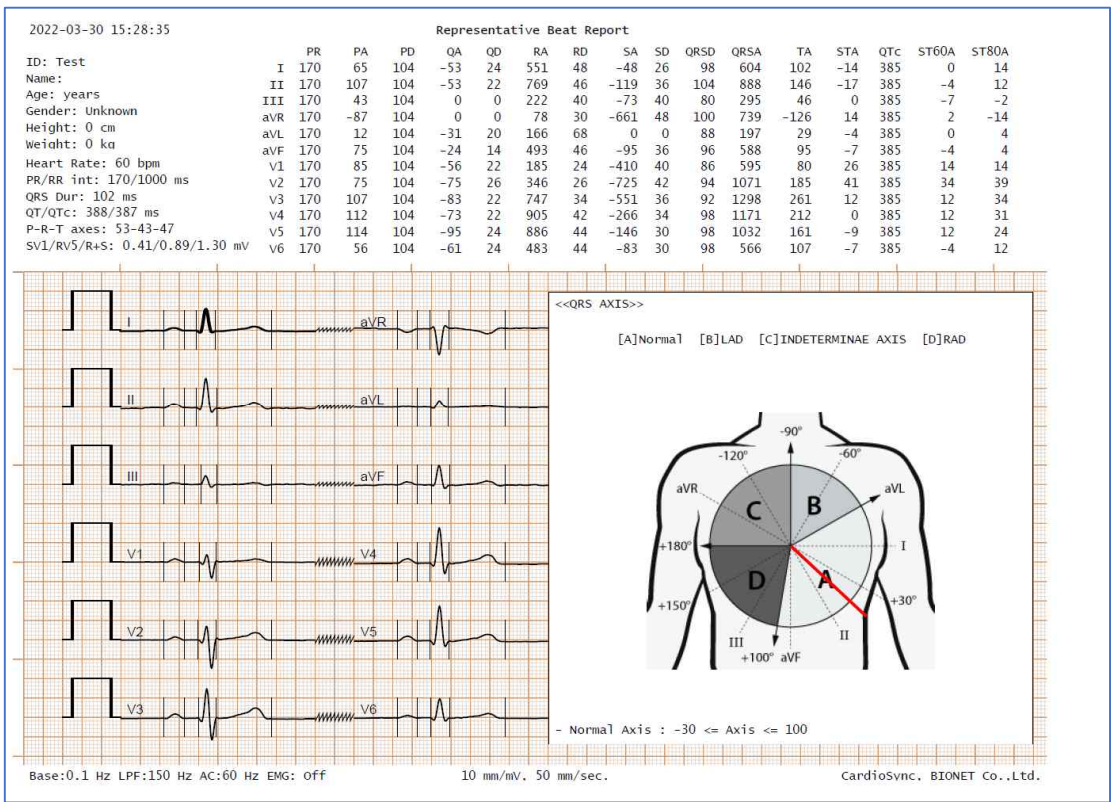


Diagnosis Print Format (BEAT REPORT-TEXT)



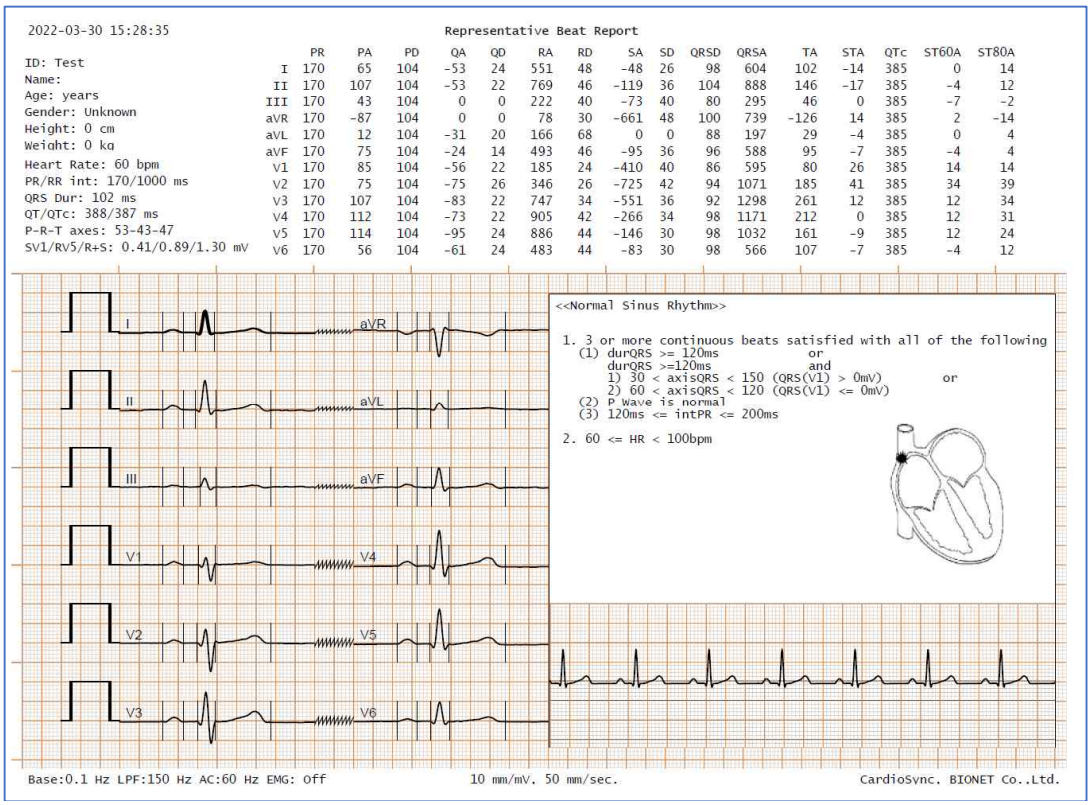
	PR	PA	PD	QA	QD	RA	RD	SA	SD	QRSD	QRSA	TA	STA	QTc	ST60A	ST80A
I	170	65	104	-53	24	551	48	-48	26	98	604	102	-14	385	0	14
II	170	107	104	-53	22	769	46	-119	36	104	888	146	-17	385	-4	12
III	170	43	104	0	0	222	40	-73	40	80	295	46	0	385	-7	-2
aVR	170	-87	104	0	0	78	30	-661	48	100	739	-126	14	385	2	-14
aVL	170	12	104	-31	20	166	68	0	0	88	197	29	-4	385	0	4
aVF	170	75	104	-24	14	493	46	-95	36	96	588	95	-7	385	-4	4
V1	170	85	104	-56	22	185	24	-410	40	86	595	80	26	385	14	14
V2	170	75	104	-75	26	346	26	-725	42	94	1071	185	41	385	34	39
V3	170	107	104	-83	22	747	34	-551	36	92	1298	261	12	385	12	34
V4	170	112	104	-73	22	905	42	-266	34	98	1171	212	0	385	12	31
V5	170	114	104	-95	24	886	44	-146	30	98	1032	161	-9	385	12	24
V6	170	56	104	-61	24	483	44	-83	30	98	566	107	-7	385	-4	12

Diagnosis Print Format (BEAT REPORT-VECTOR)

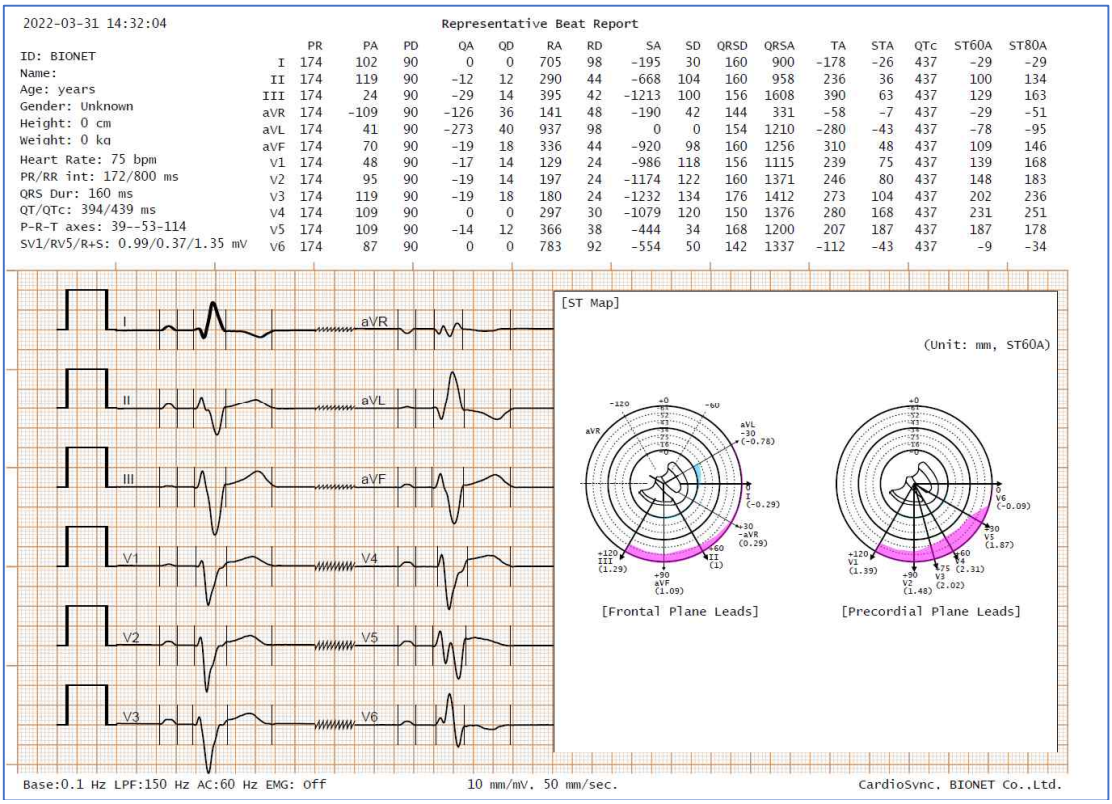


	PR	PA	PD	QA	QD	RA	RD	SA	SD	QRSD	QRSA	TA	STA	QTc	ST60A	ST80A
I	170	65	104	-53	24	551	48	-48	26	98	604	102	-14	385	0	14
II	170	107	104	-53	22	769	46	-119	36	104	888	146	-17	385	-4	12
III	170	43	104	0	0	222	40	-73	40	80	295	46	0	385	-7	-2
aVR	170	-87	104	0	0	78	30	-661	48	100	739	-126	14	385	2	-14
aVL	170	12	104	-31	20	166	68	0	0	88	197	29	-4	385	0	4
aVF	170	75	104	-24	14	493	46	-95	36	96	588	95	-7	385	-4	4
V1	170	85	104	-56	22	185	24	-410	40	86	595	80	26	385	14	14
V2	170	75	104	-75	26	346	26	-725	42	94	1071	185	41	385	34	39
V3	170	107	104	-83	22	747	34	-551	36	92	1298	261	12	385	12	34
V4	170	112	104	-73	22	905	42	-266	34	98	1171	212	0	385	12	31
V5	170	114	104	-95	24	886	44	-146	30	98	1032	161	-9	385	12	24
V6	170	56	104	-61	24	483	44	-83	30	98	566	107	-7	385	-4	12

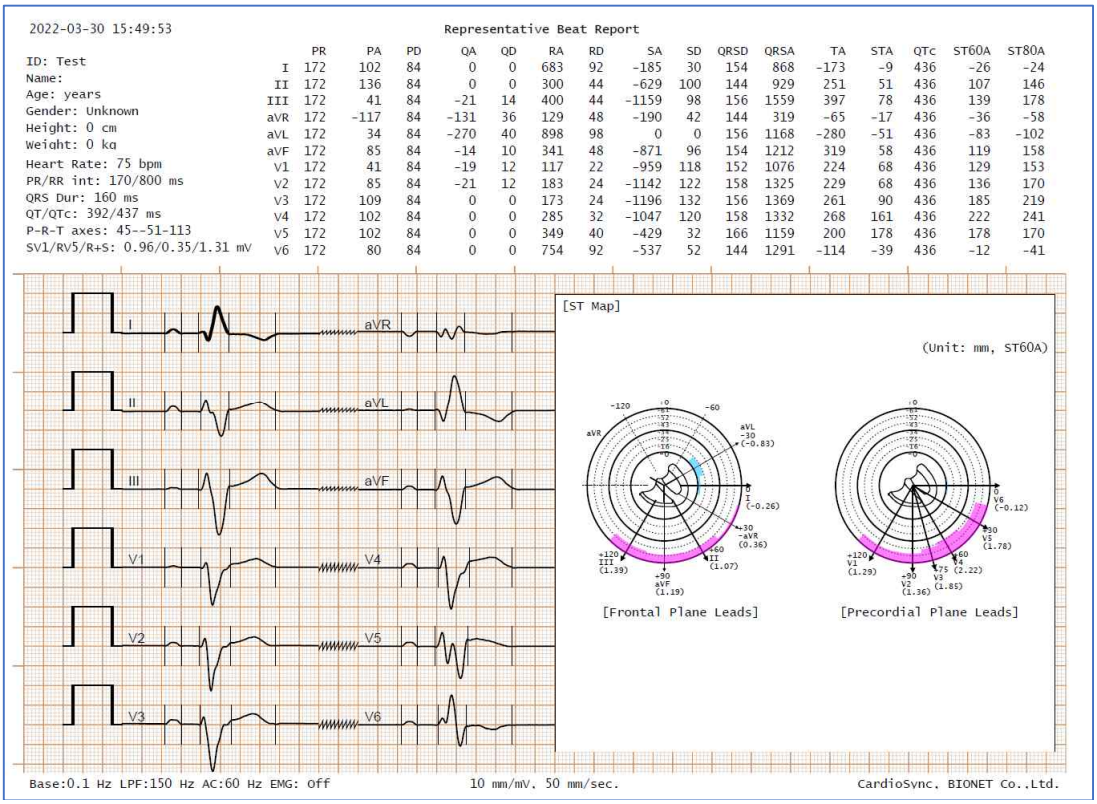
Diagnosis Print Format (BEAT REPORT-GUIDE)



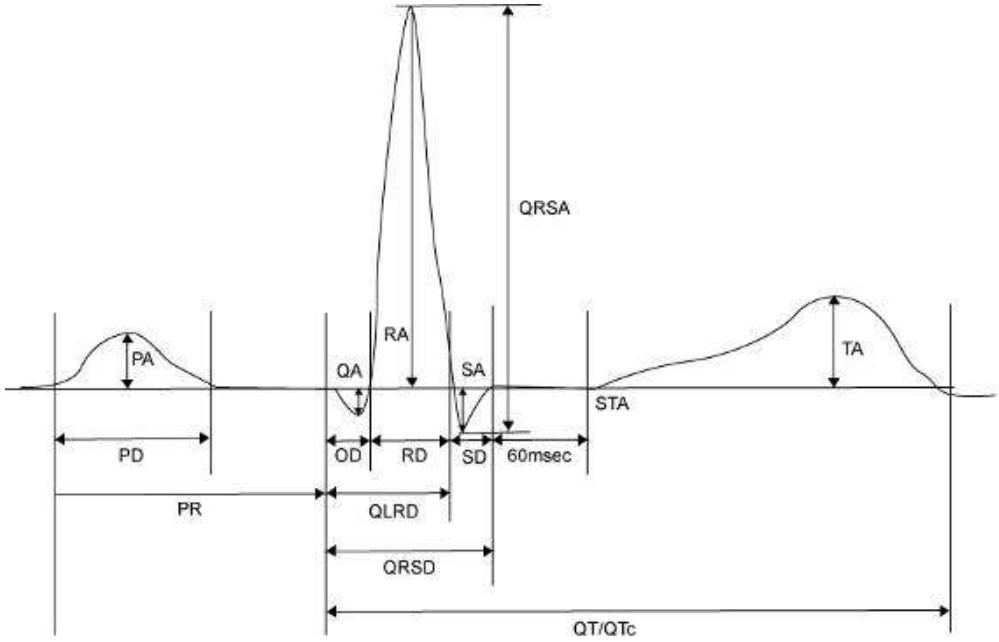
Diagnosis Print Format (BEAT REPORT-ST Map (D))



Diagnosis Print Format (BEAT REPORT-ST Map (B))



*** Explanation of BEAT REPORT Variables**



- PR: PR Interval
- PA: Amplitude of P Wave (P Amplitude)
- PD: Duration of P Wave (P Duration)
- QA: Amplitude of Q Wave (Q Amplitude)
- QD: Duration of Q Wave (Q Duration)
- RA: Amplitude of R Wave (R Amplitude)
- RD: Duration of R Wave (R Duration)
- SA: Amplitude of S Wave (S Amplitude)
- SD: Duration of S Wave (S Duration)
- QRSD: Duration of QRS Wave (QRS Duration)
- QRSA: Amplitude of QRS Wave (QRS Amplitude)
- TA: Amplitude of T Wave (T Amplitude)
- STA: Amplitude of ST Wave (ST Amplitude)
- QTc: Correct Q-T Interval (collect Q-T Interval)
- ST60A: Amplitude of ST+60ms (ST60ms Amplitude)
- ST80A: Amplitude of ST+80ms (ST80ms Amplitude)

Note
The unit of parameter intervals (duration, interval) used in the Beat Report is *ms*, and the unit of height (amplitude) is *uV*.

Note

Dextrocardia

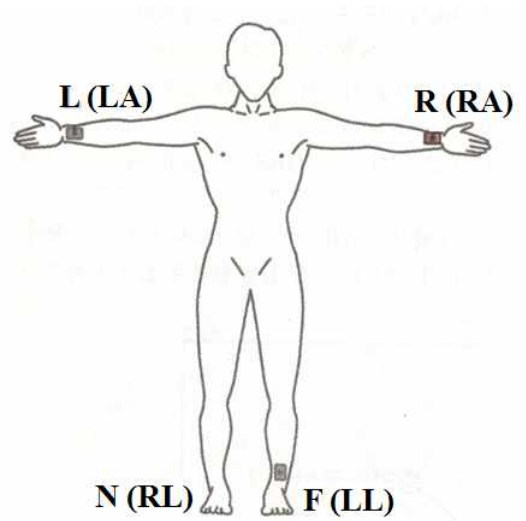
Normally, the heart is located in the left chest. However, there are cases where the heart is located in the right chest, which is called Dextrocardia.

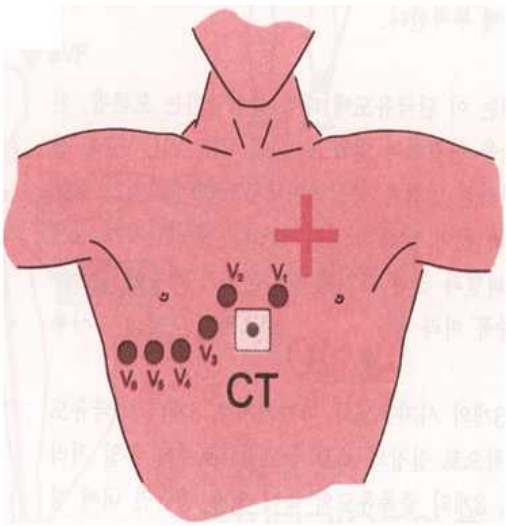
You may suspect Dextrocardia in the following cases:

- If P, QRS and T are all reversed in Lead I
- If aVR and aVL are switched, and lead II and III are switched
- If R wave becomes smaller from V1 to V6 in chest lead

For Dextrocardia patients, change the electrode positions and measure as follows to obtain auto diagnostic results correctly.

- Switch the electrodes on right hand (R) and left hand (L).
- Attach the chest lead from the left in order, which used to be attached from the right.





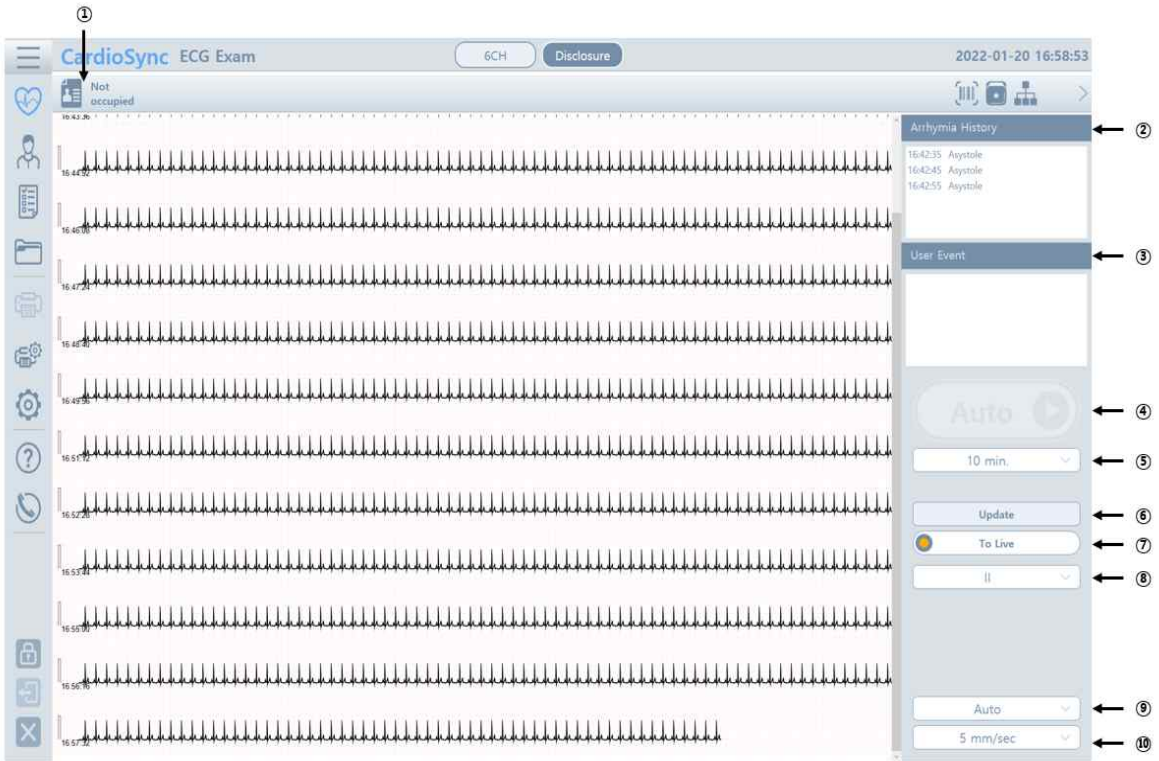
5) Disclosure

Touch the Disclosure button on the menu bar at the bottom of the ECG main screen to switch to Disclosure screen. Disclosure is a function that stores ECG data in the equipment memory and shows it when executed.

In the Disclosure screen: The pre-stored 30 minutes of ECG data are displayed in 1CH. The interval section of the pre-set mode (10 seconds, 1 minute, 3 minutes, 5 minutes, 10 minutes, 20 minutes, or 30 minutes) is marked with a square, allowing you to print diagnosis for the selected area or transmit data of the area.

Touch the graph window and select the screen output section: your touch point becomes the center of the square-marked area. Select the screen output section and press the [AUTO] key on the control panel to print diagnosis or save and transmit the data.

Refer to the following description for Disclosure screen.



① Patient ID and name: Touch this button to enter patient information.

② Number of events (Arrhythmia): Touch this button to set Event List (Arrhythmia History).

③ Event list display.

④ Selected area diagnosis execution button.

⑤ ECG recording mode display (10s, 1m, 3m, 5m, 10m, 20m, 30m) and setting menu button.

⑥ Touch the button to update EKG Wave data from the start of Disclosure to the present time.

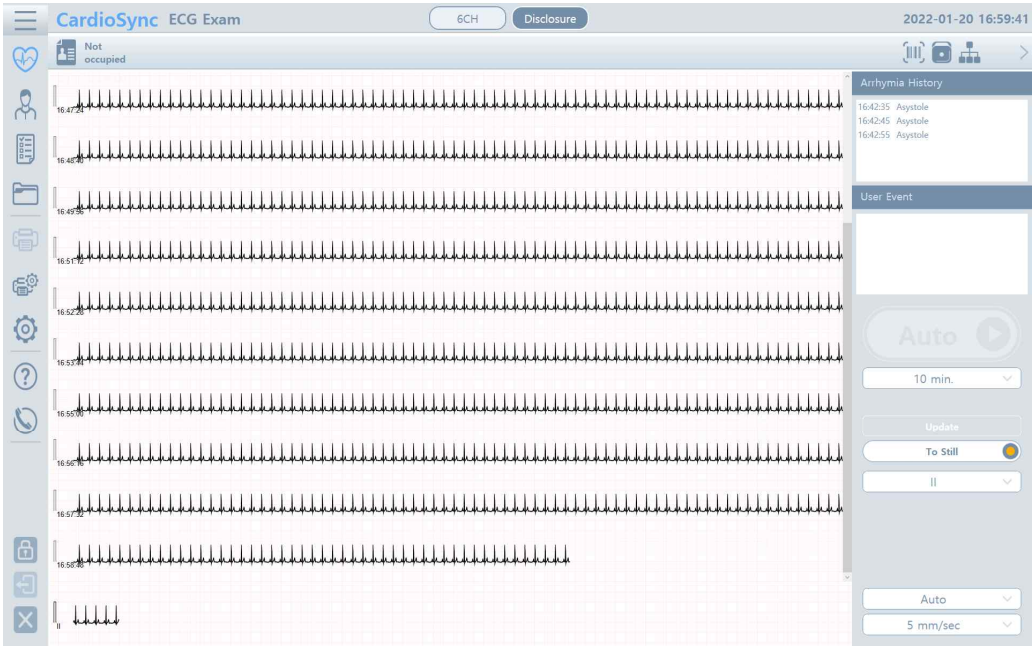
⑦ Switch to Live mode button

⑧ Select output lead

⑨ Select the output size

⑩ Output speed selection

Refer to the following description for Disclosure Live mode screen.



ECG Wave data is drawn in real time in the grid-marked area at the bottom of the screen.

The abbreviation of the diagnosis name displayed on the screen is as follows:

No.	Abbreviations	Diagnostic
1	Bigeminy	PVC Bigeminy
2	Trigeminy	PVC Trigeminy
3	Couplet	PVC Couplet
4	ShortRun	Short run of PVC
5	Vtachy	Ventricular Tachycardia
6	Vrhythm	Ventricular Rhythm
7	Vbrady	Ventricular Bradycardia
8	Paced	Pacemaker Rhythm
9	PVC	PVC
10	Asystole	Asystole
11	Pause	Pause

12	Irregular	Irregular
13	RonT	R on T

Arrhythmia Template

No.	Diagnostic	Description
1	PVC Bigeminy	Occurs when two or more bigeminal cycles (a ventricular beat followed by a non-ventricular beat) are detected.
2	PVC Trigeminy	Occurs when two or more trigeminal cycles (a ventricular beat followed by two non-Ventricular beats) are detected.
3	PVC Couplet	Occurs when two ventricular beats are detected and have non-ventricular beats before and after the couplet. The coupling interval must be less than 600 milliseconds.
4	Short run of PVC	Occurs 3~5 continuous Ventricular Premature Beats.
5	Ventricular Tachycardia	Occurs when six or more ventricular beats are detected when the average heart rate is greater than or equal to 100 beats per minute.
6	Ventricular Rhythm	Occurs when six or more ventricular beats are detected with an average heart rate for the ventricular beat between 50 and 100 beats per minute.
7	Ventricular Bradycardia	Occurs when a run of three or more ventricular beats is detected with an average heart rate that is less than or equal to 50 beats per minute.
8	Pacemaker Rhythm	A pacemaker is indicated when electrical impulse conduction or formation is dangerously disturbed. It shows pacemaker spikes: vertical signals that represent the electrical activity of the pacemaker.
9	PVC	Isolated premature ventricular complexes occur when a premature ventricular beat is. Detected and has non-ventricular beats before and after.
10	Asystole	Ventricular asystole occurs whenever the displayed heart rate drops to zero.
11	Pause	Occurs when the interval between two consecutive beats exceeds three seconds.
12	Irregular	Occurs when six consecutive normal R-to-R intervals vary by 100 milliseconds or more.
13	R on T	Occurs when a ventricular complex is detected within the repolarization period of a Non-ventricular beat.

Note
The diagnosis provided by Cardio P1 must be confirmed by a qualified medical professional.

6) One-key Diagnosis (AUTO key)

Press the [AUTO] key shortly to diagnose the ECG acquired during the set duration, and to save, transmit, and print the result. It functions according to the [AUTO] key settings set in System General Setup.

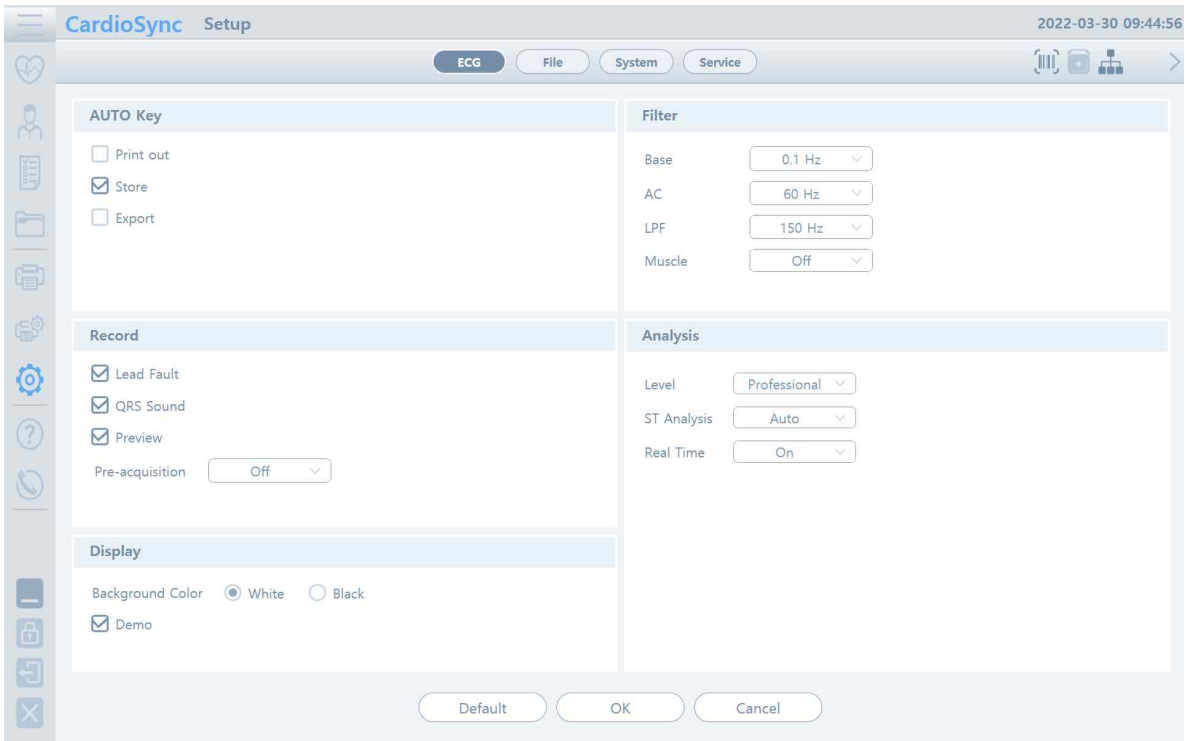
Press and hold the Auto Event key longer than 3 seconds to diagnose the ECG acquired during the set duration and to print the result.

7) System Setup

The Setup menu is used to set various contents related to the equipment.

You can set it by clicking the Settings button on the left side of the screen.

ECG Setup

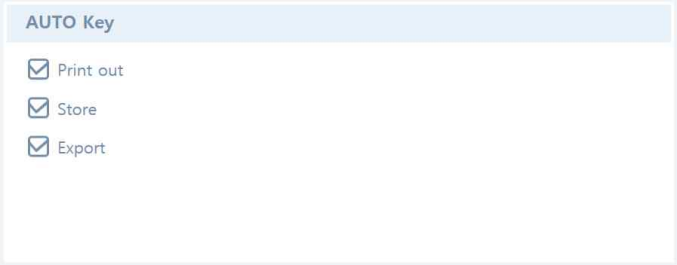


If you select the 'Settings' button on the left menu bar of ECG, you can change the setting conditions. You can setup ECG related setups in each group.

'Default' button is shown on the setup currently shown on the screen.

If saving changed information after all the setups, select 'Ok' button. If cancelling, select 'Cancel' button.

AUTO Key



Setup auto key of control panel.

Available to setup the saving, printing, and transmitting as follows.

Store

Setup whether to save measured data.

If set to be 'ON,' results are automatically saved in the internal memory after the measurement. If set to be 'OFF,' data are not saved.

Saved data are available on the 'file' main screen.

Print out

Setup whether to print measured data.

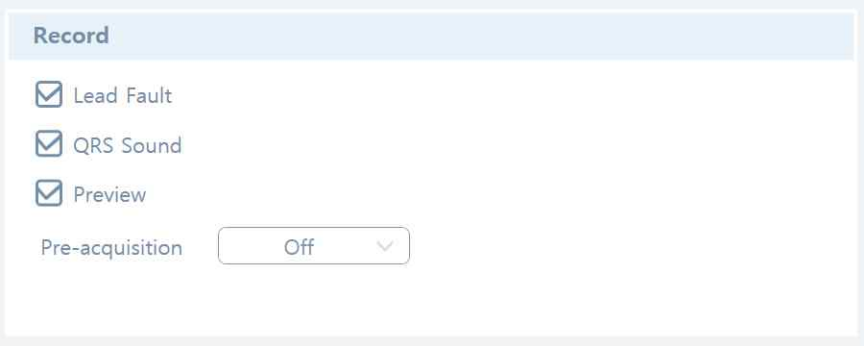
Print measured data if set to be 'ON.' If set to be 'OFF,' data are not printed.

Export

Set whether to send measurement data to an external device.

-For setting of output location, refer to 'Chapter 4 Manage Data Files- 3) Setup - File Export'

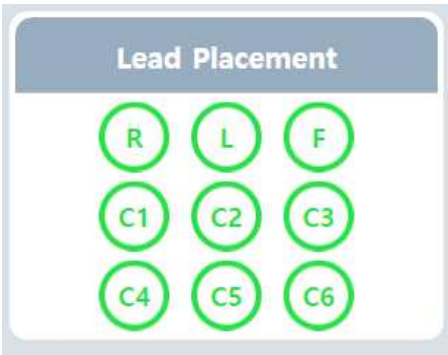
Record



Make settings related to ECG measurement.
You can set the lead fault, heartbeat alert, and preview as follows.

Setting Lead Fead Lead Fault

A lead fault may occur if the lead connection of the patient cable is unstable. Set whether or not to display the Lead Fault message in this case.
Set it to On to show a Lead Fault message or Off not to.
Lead Fault message is displayed at the top center of the ECG Main screen as follows.



Note
- If RA Lead is faulted, no waveform is displayed. - If LA Lead is faulted, waveforms of I and V1 ~ V6 Leads are not displayed. - If RL Lead is faulted, Lead Fault does not appear and waveforms of all Leads can be displayed. - If LL Lead is faulted, waveforms of II and V1 ~ V6 Leads are not displayed. - If a lead fault occurs during monitoring or recording, a message is displayed with a beep. - When a lead fault occurs, the pacemaker signal may not be detected. As it may affect the diagnosis, measure ECG again if a lead fault occurs.

QRS Sound

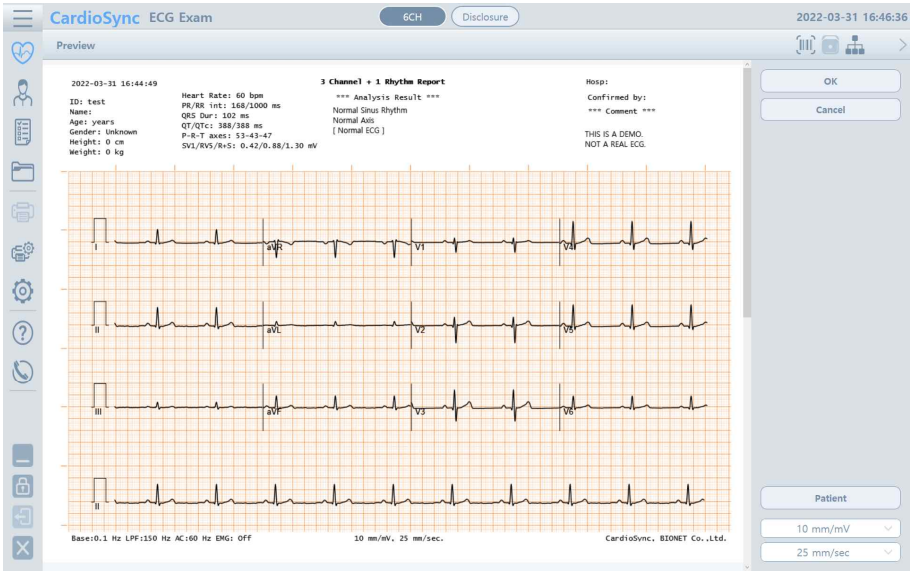
You can set the sound output according to the QRS beat.

When it is set to On, a sound is generated from the QRS beat, and when it is Off, no sound is produced.

Preview

Preview shows the results of measurement in advance after performing the diagnosis with record, auto and network keys. If setting up the preview function, it is required to select 'On,' or 'Off' for vice versa.

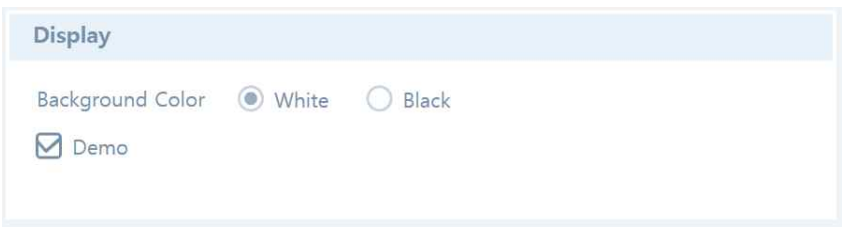
If selecting 'Ok' on the preview screen, function of each key including the printing, saving, or transmitting is performed. If selecting 'cancel,' it is cancelled.



Pre-acquisition

Set whether to acquire ECG information in advance, up to 10 seconds

Display



Make settings related to the screen display.

You can set the background color and demo display as follows.

background color

You can set the background for drawing the graph.

In the case of Grid, a red grid and black signal are displayed on a white background, and in the case of Black, a green signal is displayed on a black background.

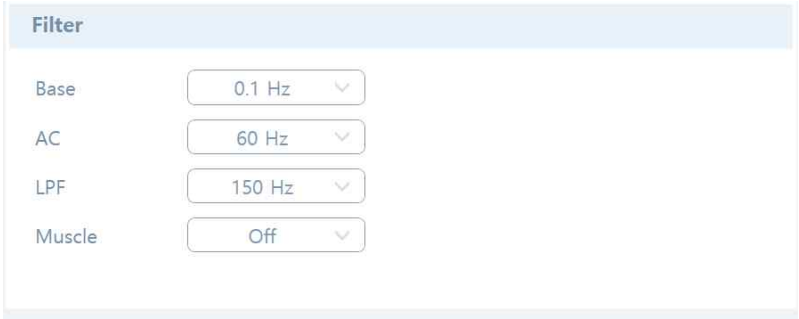
Demo

Setup or discharge demo functions. If set to be ON, 60bpm Sinus Normal Rhythm signals are shown on the screen and 'Demo' is shown in the middle of screen. You can test all the functions including rhythm, diagnosis, copy and communication.

If turning the equipment off and on, demo function is discharged.

Filter Setup

Power noise, baseline drift from breathing and EMG might be recorded as well besides ECG data on the acquired signal of ECG. Therefore, when the signal is bad, a good ECG signal can be obtained by using the filter properly.



Base

Baseline drift is noise occurring from respiration of a patient recording ECG on a huge arc. Baseline filter can be applied as 0.05Hz, 0.1Hz and 0.2Hz in the base menu.

AC

AC filter is a power noise removing filter and can be setup to off, 50Hz and 60Hz. 'Off' means not to remove power noise. 50Hz and 60Hz indicate to remove 50Hz of power noise and 60Hz of power noise, respectively. Europe and China use 50Hz and Korea and America use 60Hz as setup value. When using PC battery power, there is almost no noise. Therefore, ECG can be well recorded with 'off.'

LPF

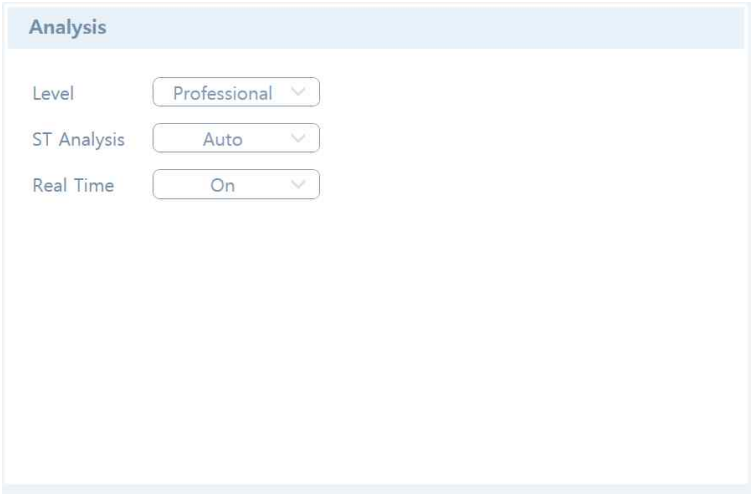
LPF filter is a low frequency filter providing off, 40Hz, 100Hz and 150Hz. 40Hz means to remove all the signals with 40Hz or above.

Muscle

Muscle filter is EMG filter as a signal that occurs in muscle or organ of a patient. If measuring ECG with patients with especially high EMG, ECG is not well recorded. Therefore, it is required to remove noise. If applying ECG filter, 'off' can be selected if not using 'on'.
Setup of all the applied filters is indicated at the left bottom corner of output form.

Note
It is recommended to apply baseline drift filter is 0.1Hz and AC filter is 50Hz or 60Hz at all times and appropriately use the EMG filter. In addition, it is also recommended to setup LPF to 150Hz in case of diagnosis output. The best quality signal can be obtained when the recommended filter is used, otherwise the signal quality may be poor.

Analysis



Level

This is the automatic diagnosis level setup menu for 10 seconds of recording.
In case of 'Basic,' diagnosis reference value is higher showing only the severe diagnosis names.
In case of 'Professional,' various diagnosis contents are shown according to the standard diagnosis values.

ST Analysis

It is about the setup of ST segment diagnosis during the 10 seconds of recording automatic diagnosis.
In case of 'Auto,' J points related to ST level are automatically setup. In case of '60msec,' J points

are set to be 60msec. In case of '80msec,' J points are set to be 80msec.

Real Time Diagnosis

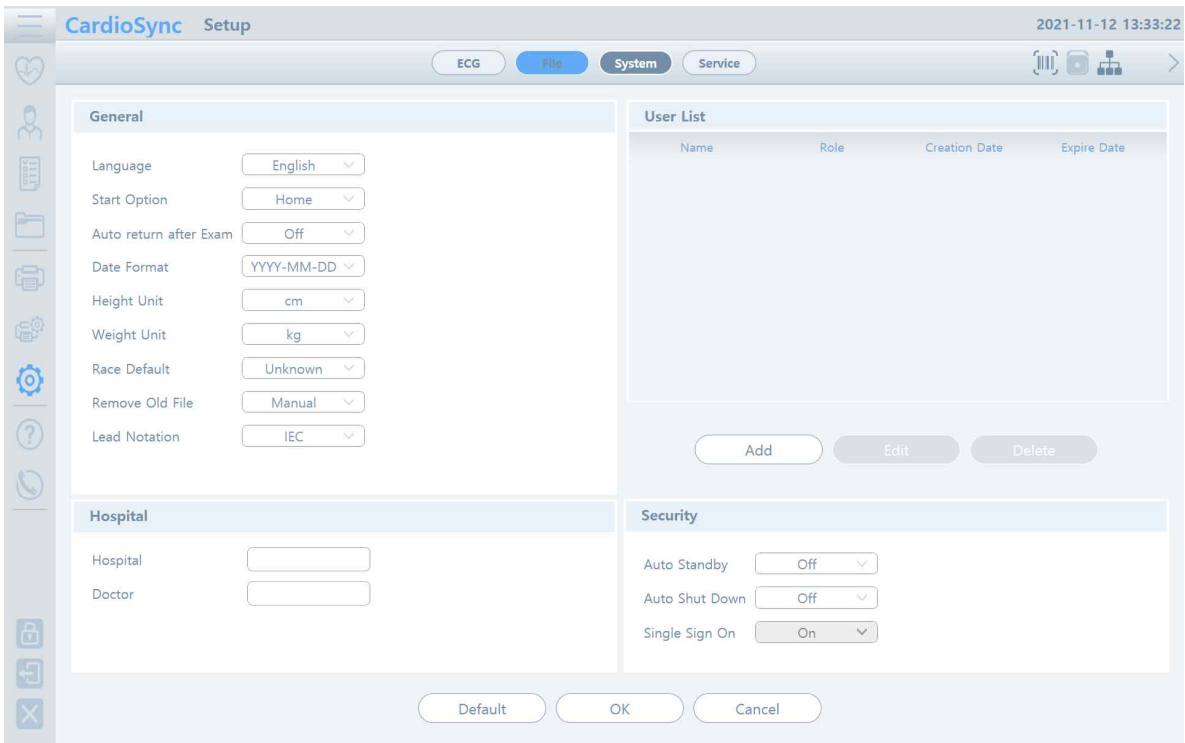
This is the setup for real-time automatic diagnosis on the ECG main screen.

If detecting arrhythmia in the standby condition without recording, you can set it to 'ON' to show the diagnosis name.

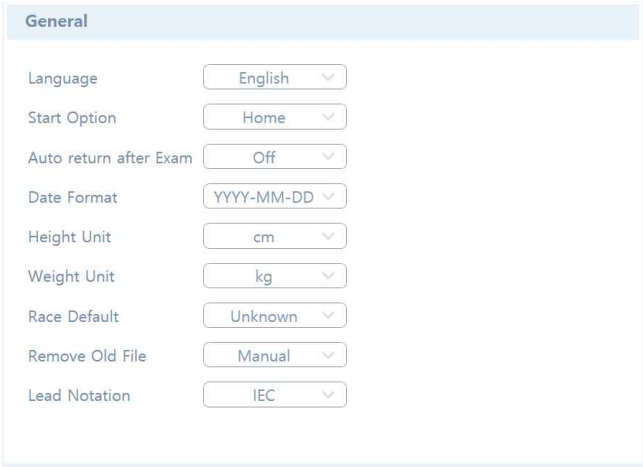
If set to be 'On,' diagnosis name of arrhythmia is indicated on the top of ECG main screen in case of arrhythmia.

System

Setup the system. It is available to setup general, hospital, server, and service in each group.

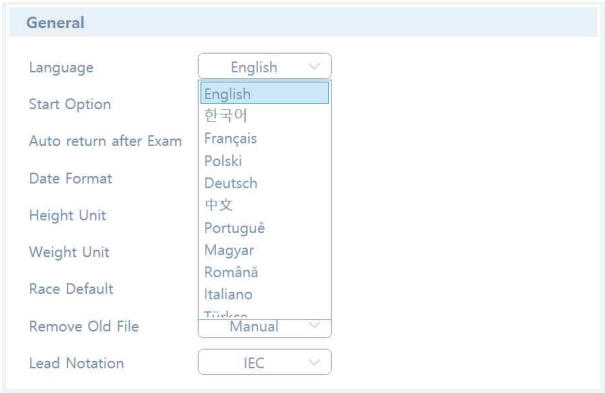


General



Language

Select the language and touch [OK].



Note
Even if the set language is not English, some terms, such as diagnosis names, may be shown in English.

Start Option

This is to setup the screen shown when the equipment turns on for the first time. Make sure to select the default screen with function that is frequently used among main, ECG, Patient, file and worklist.

Auto return after Exam

- Off : Return to the measurement screen after the end of the test
- Worklist: After the inspection is finished, it goes to the Worklist screen.
- Review: Go to the Review screen after completing the test.

Date Format

Setup the date format.

Set format is applied to the screen and also the printing.

Height Unit

Setup the unit used for height entry of a patient. Cm and inch are available.

Weight Unit

Setup the unit used for weight entry of a patient. Kg and lbs are available.

Race Default

If the patient's race is not entered, you can select the race that will be selected by default.

Remove Old File

Set how old files are removed

- Manual: Ask the user whether to delete the oldest files
- Auto: Automatically deletes the oldest file and saves the measured file

Lead Notation

You can select either IEC or AHA to mark each lead.

Hospital

Hospital Information

Enter hospital name.

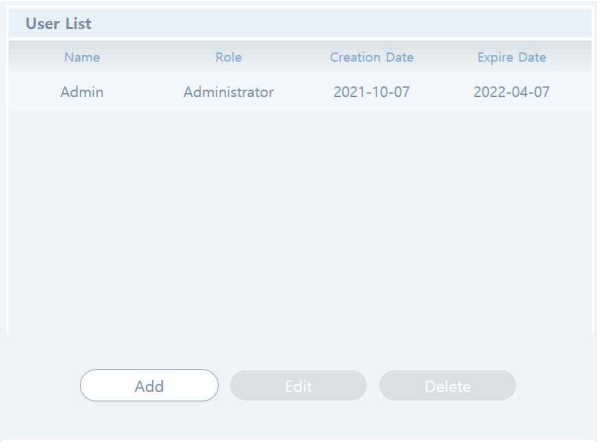
Doctor Information

Enter doctor name.

Location Information

Enter location name.

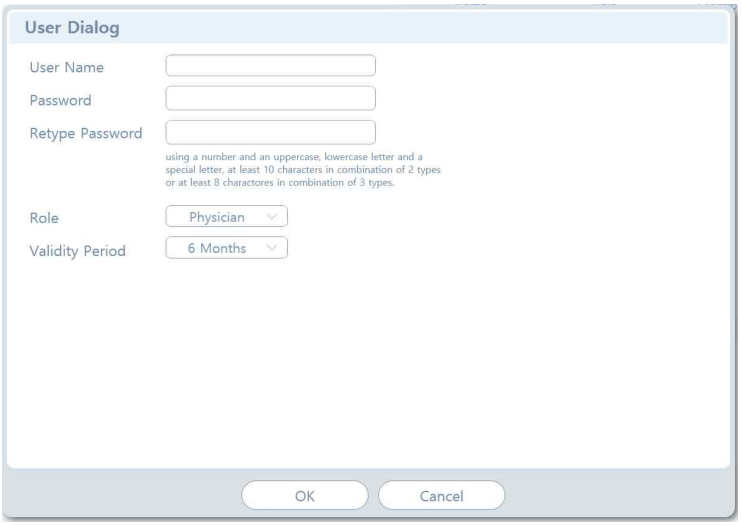
User List



Manage who will use the program.

User Add

Click Add user to enter a new user.



- User Name : Enter the user name
- Password : Enter the user's password.
- Retype Password: Confirm by re-entering the user password.

- Role : Enter the user's permissions. In case of 'Admin,' user has authority over all functions, such as system setting, diagnosis setting, inspection, general setting and etc. In case of 'Physician,' user has authority over diagnosis settings, tests, general settings. In case of 'Technician,' user has authority for inspection, general settings.
- Validity Period : Set the expiration date of the user account.

Note
Rules for Creating Passwords - 10 or more characters: a combination of two of uppercase letters, lowercase letters, numbers, and special characters. - 8 or more characters: 3 combinations of uppercase letters, lowercase letters, numbers, and special characters.

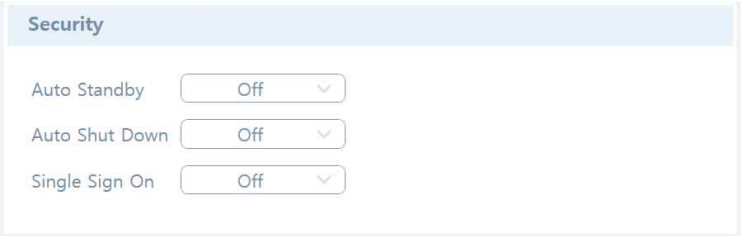
User Edit

Click Edit User to edit the clicked user information.

User Delete

Click Remove user to remove the clicked user information.

Security Setup



Auto Standby

Set On/Off to shut down the equipment when not used for the timeout period.

Set the timeout period to off, 10min, or 30min. If not used for a set period, the equipment will automatically shut down.

Auto Shutdown

Set the device to automatically shut down when not in use for a certain period of time.

Off, 10min, 20min, 30min can be set and the equipment is automatically shut down if not used for the set time.

Single Sign On

Because single sign-on can compromise security, Bionet recommends this setting only for the devices used single or a limited user.

Activate it to enable system authentication of user ID and password.

If it is set, no login is required at the start of the program because user authentication is carried out by the equipment.

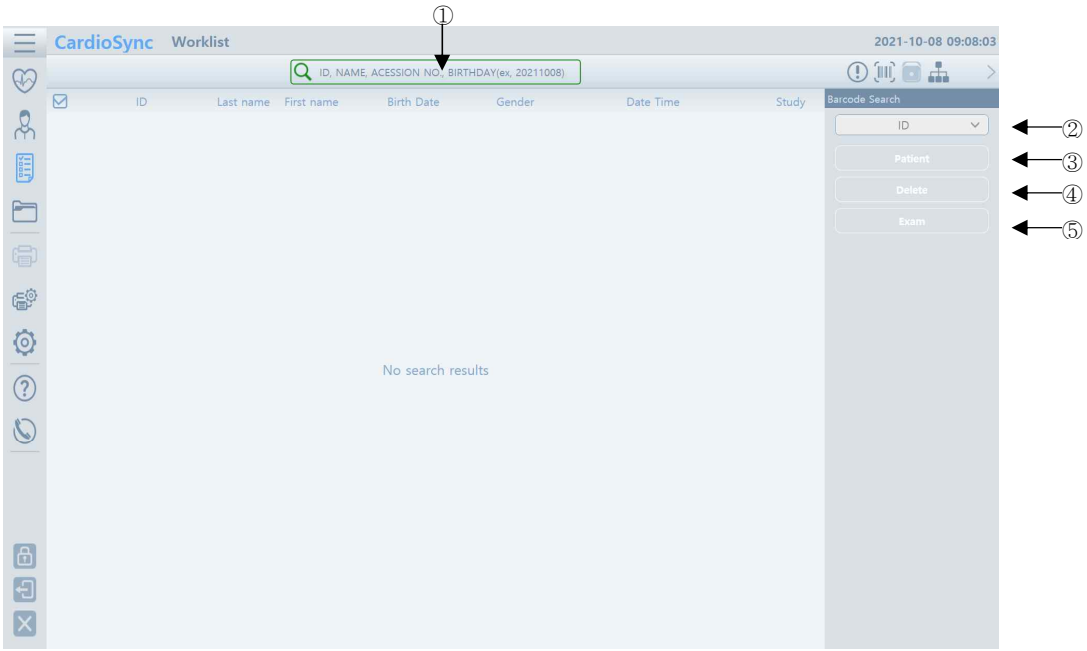
Also, if the application timeout is set, you do not need a password to reactivate the application.

Settings are only available with an administrator account.

Part II. Data and System Management

Chapter 3. Exam-requested Data Management

1) Screen Description



① Top list search menu button

② Search condition setting button

③ Retrieve patient information button

④ Delete selected information button

⑤ Test progress button

2) Function

Search

You can enter search conditions by clicking the search condition menu at the top right of the screen. The search condition menu window is activated only when PACS is linked.

Touch the magnifying glass button at the top left of the screen to enter a search condition.
Touch Search Item to enter ID, Name, Accession No.

View patient information

You can check or change patient information in the selected list.

Get inspection information

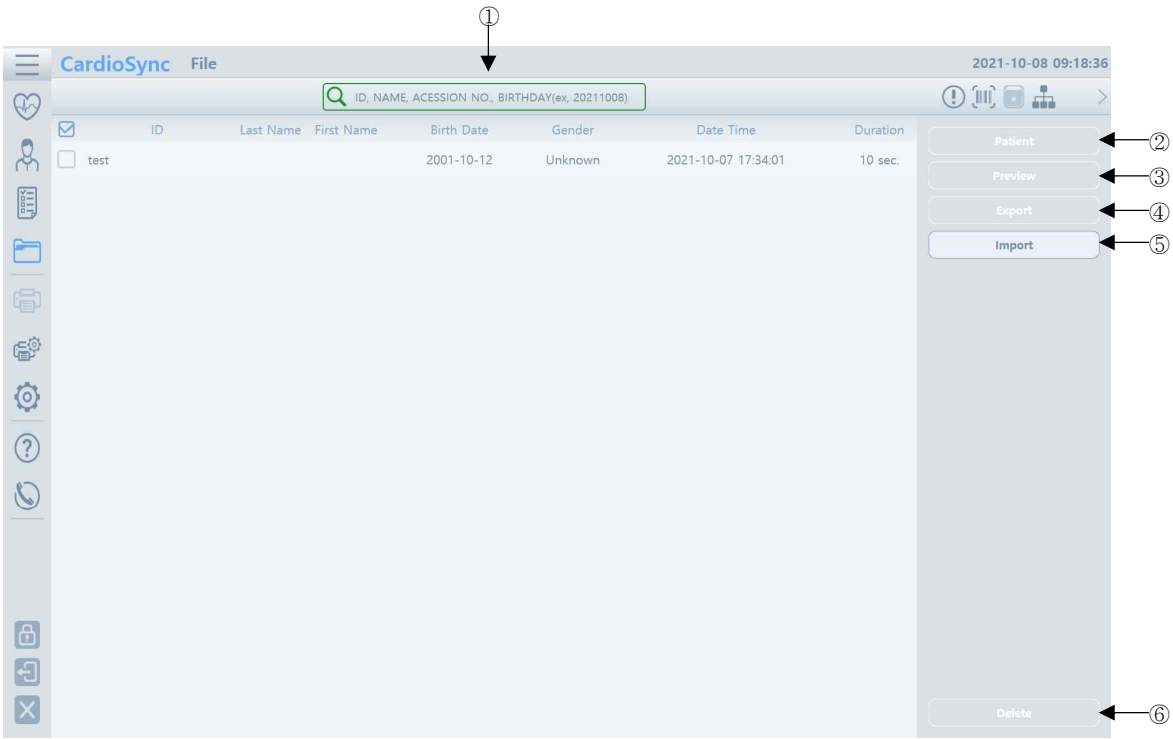
Get the latest inspection information from the PACS server or GDT server.
The 'Update' menu is displayed only when connected to the PACS server or GDT server.

Examination

Click the 'Exam' button to move to the ECG main screen for ECG examination with patient information from the selected worklist.

Chapter 4. Manage Data Files

1) Screen and Function Setup



① File list search menu button

② View selected patient information button

③ Selected file preview button

④ File export button

⑤ File import button

⑥ Delete file button

2) Function

Search File(ID, NAME, BIRTHDAY)

You can enter search conditions by clicking the magnifying glass input box at the top center of the screen.

Delete Files

Delete selected files. It is available to delete one or multiple files.

Note
Care has to be taken as deleted data cannot be restored.

View Files

Preview of selected files

It is available to change and print speed, gain, and print form on the preview screen.

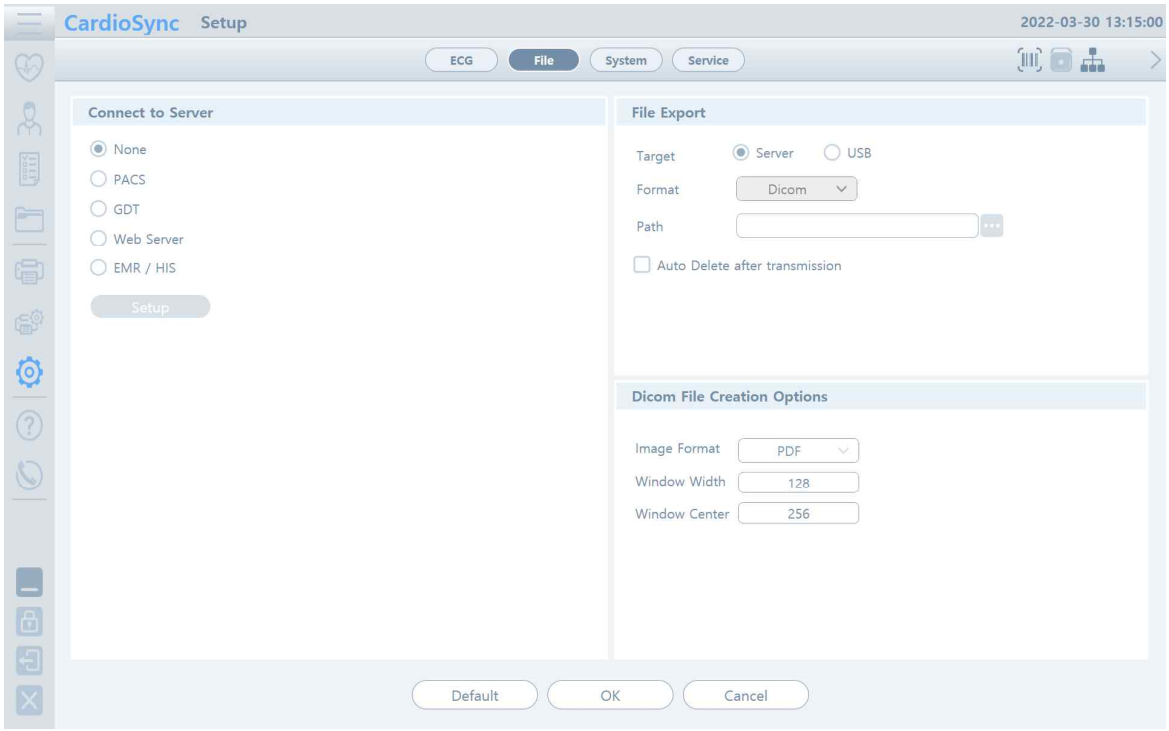
View Patient Information

It is available to confirm or change patient information on selected files.

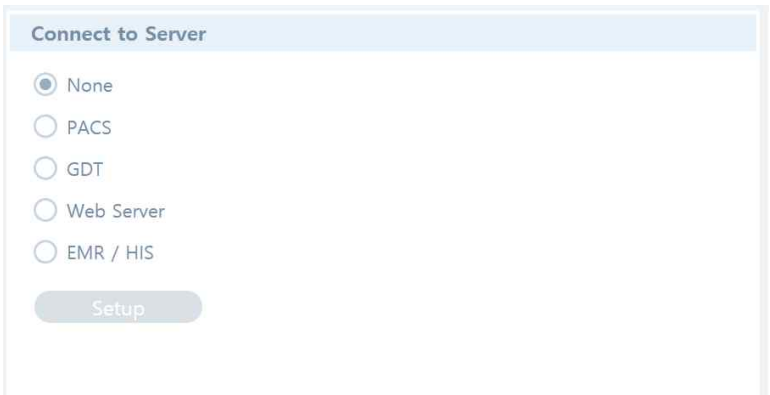
Note
When recording ECG for 10 seconds, adult diagnosis is applied to those aged 16 or above. However, for children under the age of 16, the pediatric diagnosis algorithm is applied.

3) Setup

If clicking 'setup' button on the menu, 'file setup' window pops up.



Connect to Server



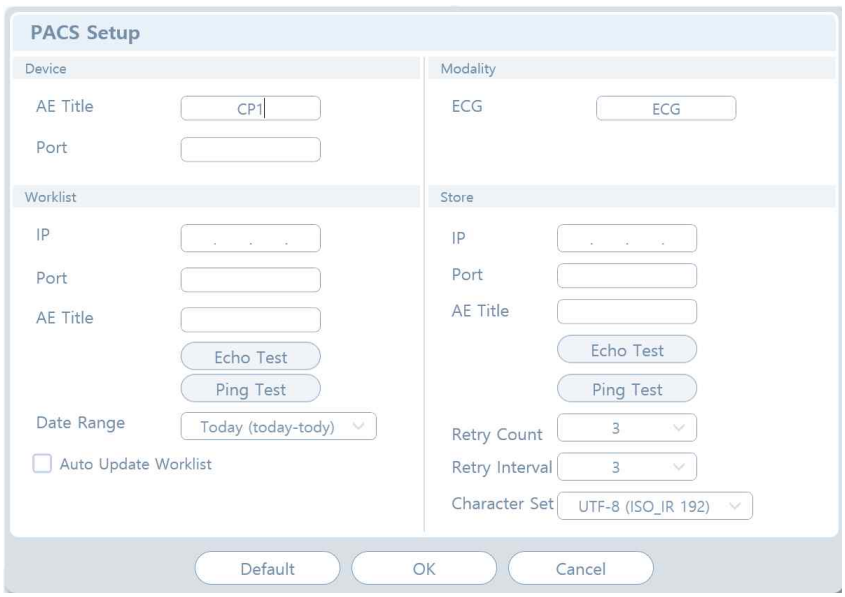
PACS, GDT, Web server or EMS/HIS can be selected from the menu to select the server interlocked with the equipment.

After selecting the type of server to be linked, select the 'Edit' button to display the server setting window.

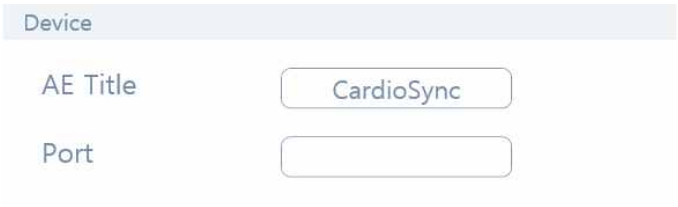
A. None

No connection with the server.

B. PACS Setting



Device Information



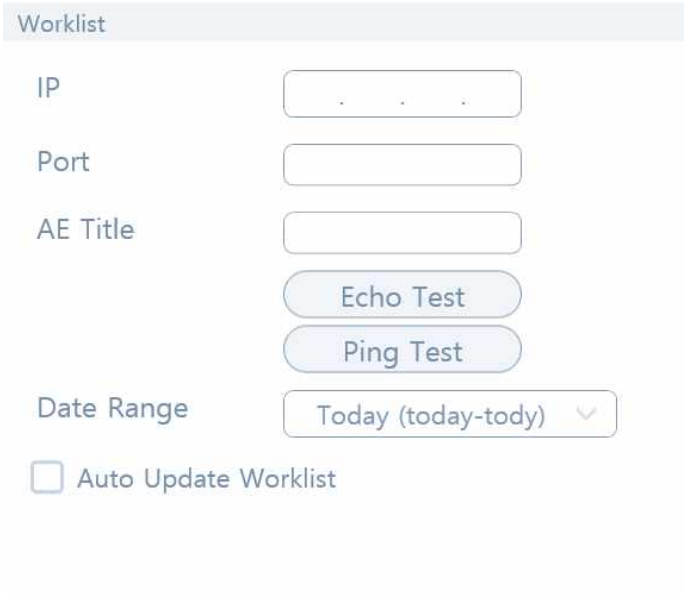
AE Title, Port

Enter information such as AE Title and Port of Cardio P1.

Modality

Enter the Modality of ECG

Worklist Server Settings



IP, Port, AE Title

Worklist Enter information such as the server's IP, AE Title, Port, etc.

Server connection check

You can check the worklist server connection by pressing the 'Echo Test' button after entering the information of the worklist server. Click the "Ping Test" button to check the task list and ping.

Select date range

You can set the date range from which worklists are fetched from the Worklist server.

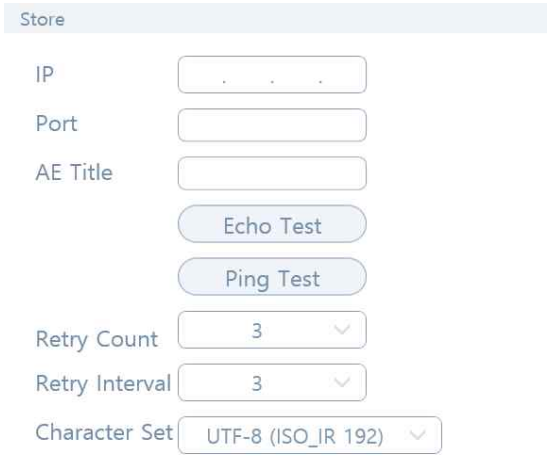
List	Description
Today (today-today)	Get the worklist for today's date. Set both start and end dates to today.
Today (today-blank)	Get the worklist for today's date. Get the worklist by setting only the start date to today
Yesterday~Tomorrow	Get the worklist from yesterday to tomorrow.
One Week	Get a worklist from today to a week from now.
A Week ago	Get the worklist from a week ago to today.

Auto Update Worklist

If you check Auto Update Worklist, the latest worklist is automatically imported every time you

enter the worklist screen.

Store Server Settings



IP, Port, AE Title

Enter information such as IP, AE Title, and Port of the Store server.

Echo Test & Ping Test

After entering the store server information click the “Echo Test” button or “Ping Test” button to check the connection to the store server.

Retry Count

Select the number of retransmission attempts when a communication error occurs while sending data to the Store server.

Retry Interval

Select the interval between retransmission attempts when a communication error occurs while sending data to the Store server.

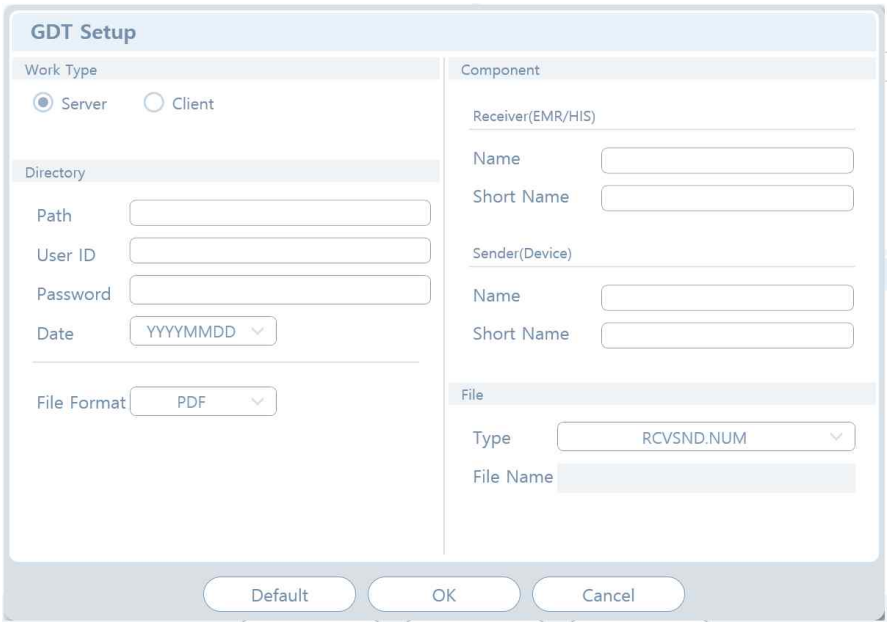
Character Set

You can select a character set for each language.
When sending a file to the PACS server, an appropriate character set must be set in order to display the contents of the characters according to each language.

Note
- When setting up a connection with the PACS server, the Device IP must be manually entered and used. When setting with DHCP, the Device IP may be changed, and if it is set differently from the equipment IP registered in the PACS server, it may not work with the server.

C. GDT Setting

When selecting GDT, additional information must be set through the Setting menu.
A screen for setting related settings such as Work type, GDT Directory, Component name, File name, Image type appears.



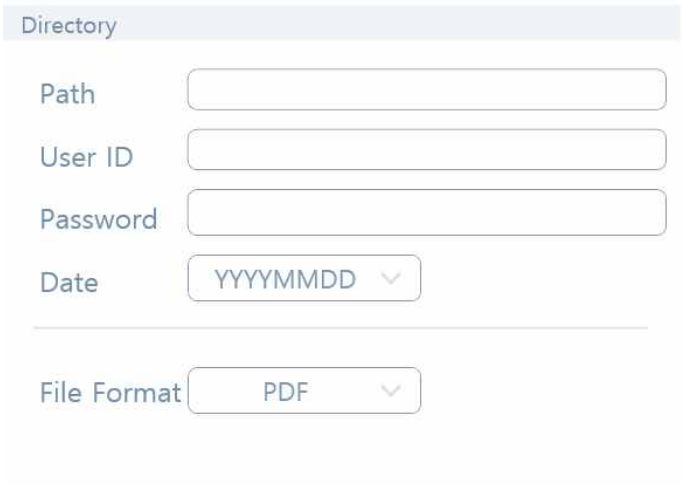
Work type

It sets how the GDT function of the device operates.

- Server: Cardio P1 receives requests and commands.
- Client: Cardio P1 sends requests and commands.

Directory

Enter the format of sharing folder information and date information to be used by GDT protocol.



Path

Enter the shared folder path to be used by the GDT protocol

ex) ₩₩192.168.30.162/GDTShare

User ID & Password

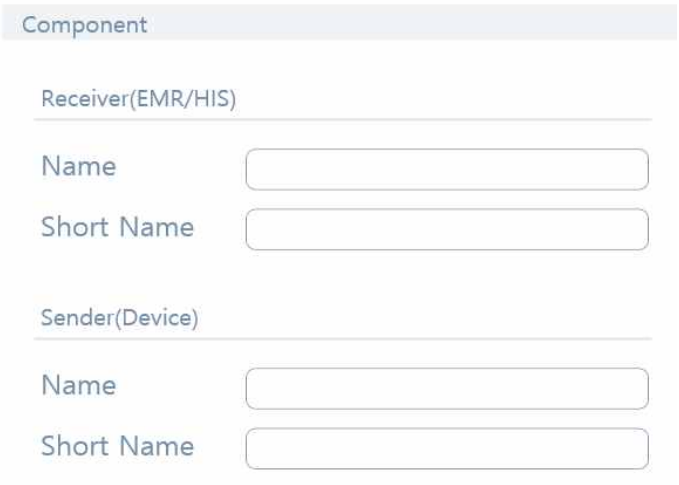
Enter shared folder access ID & password

Date

Date information format setting

- YYYYMMDD, MMDDYYYY, DDMMYYYY

Component



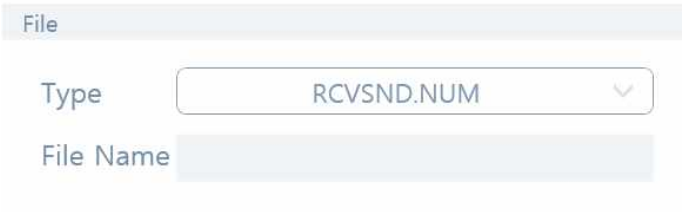
Receiver (EMR/HIS)

- Name: Enter the EMR name to use for the GDT protocol
- Short Name: Enter EMR abbreviation

Sender (Device)

- Name: Enter the device name to use for the GDT protocol
- Short Name: Enter device abbreviation

File



Type

Select the image format of the data file to be shared with the GDT protocol.

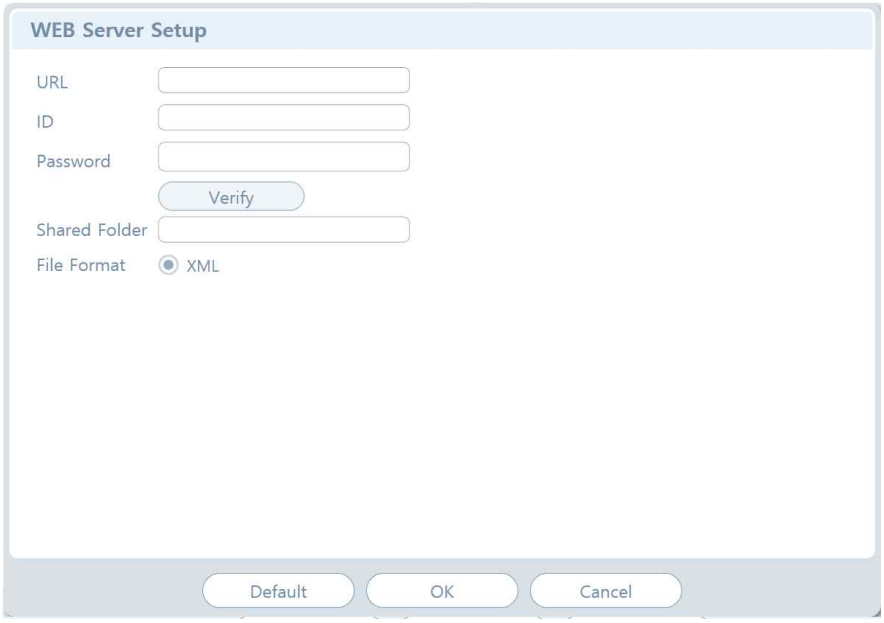
File name

Select the file name type to be shared by GDT protocol.

If you select the input window of each item, a keyboard window appears, and you can enter the relevant content.

WEB Setting

When web transmission is selected, additional information must be set through the Setting menu.
A screen for setting related settings such as DNS Server, URL, ID, PW, and Path appears.



URL

The web address to connect to.

ID

User ID to use on the web to connect to.

PW

This is the user password to use on the web to access.

Verify

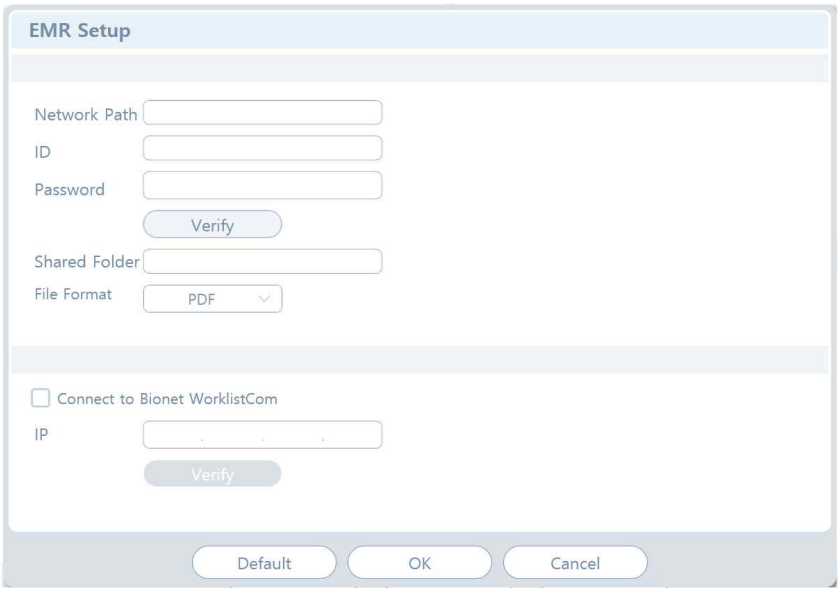
After entering the Web server information click the "Verify" button to check the connection to the Web server.

Shared Folder

The path within the server to transfer the file to.

If you select the input window of each item, a keyboard window appears, and you can enter the relevant content.

D. EMR / HIS Edit



Network Path

Enter network path

ID & Password

Enter the ID & Password

Verify

After entering the EMR information click the "Verify" button to check the connection to the EMR.

Shared Folder

Write the shared folder path on the server in the shared folder

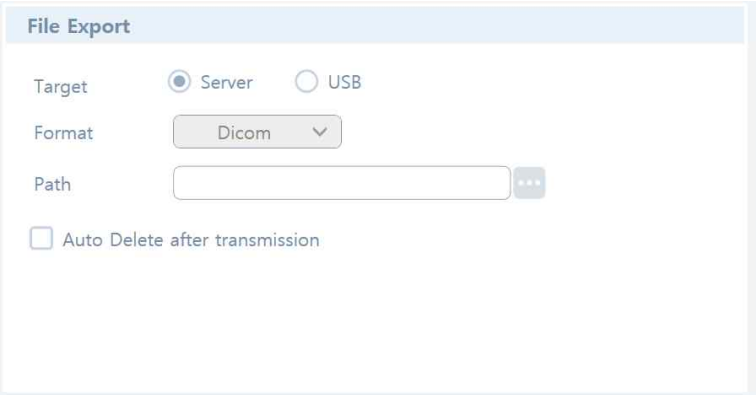
File Format

Choose a file type to decide which files to share.

WorklistCom

To manage worklists using WorklistCom provided by Bionet, check 'Connect to Bionet WorklistCom'. After entering the IP of the target using WorklistCom, you can check whether the verification button works normally by pressing the 'Verify' button.

File Export



Target

When transferring files by pressing the 'Auto' button on the ECG screen, or by pressing the 'Export' button, set the medium to be transferred. It can be set to USB memory or server.

When set to Server, you can select the server in System Server Setup.

Format

Set the format of the file to be created by transferring the file.

In addition to the Bionet format, you can select formats such as Dicom, PDF, MFER, XML, BMP, JPG

Note
The Dicom format with MFER, XML, and Image format is RAW can only support a 10-second ECG test.

Auto Delete after Transmission

Set whether to delete the file in Cardio P1 after completing the file transfer to the server.

When set to 'On', the device file is deleted after file transfer.

Note
The Delete option only applies when sending to the server. Files are not deleted when transferring to USB memory.

Dicom File Creation Option

Image Format

Determines the image format to use when transferring Dicom files.

You can choose from PDF, BMP, JPEG, and RAW.

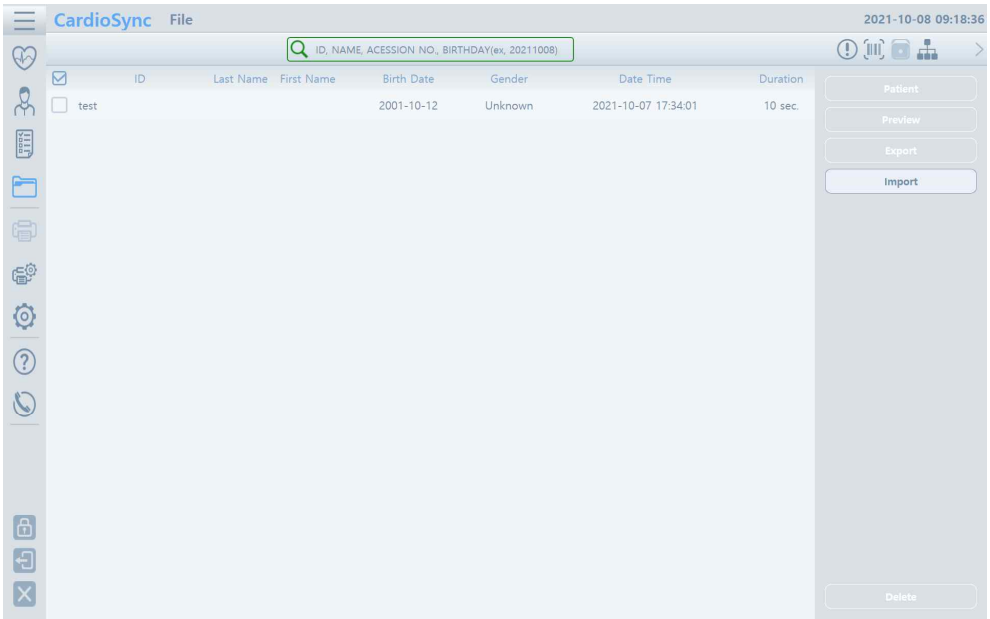
Window Width

Specifies the image size in JPG, BMP format.

Window Center

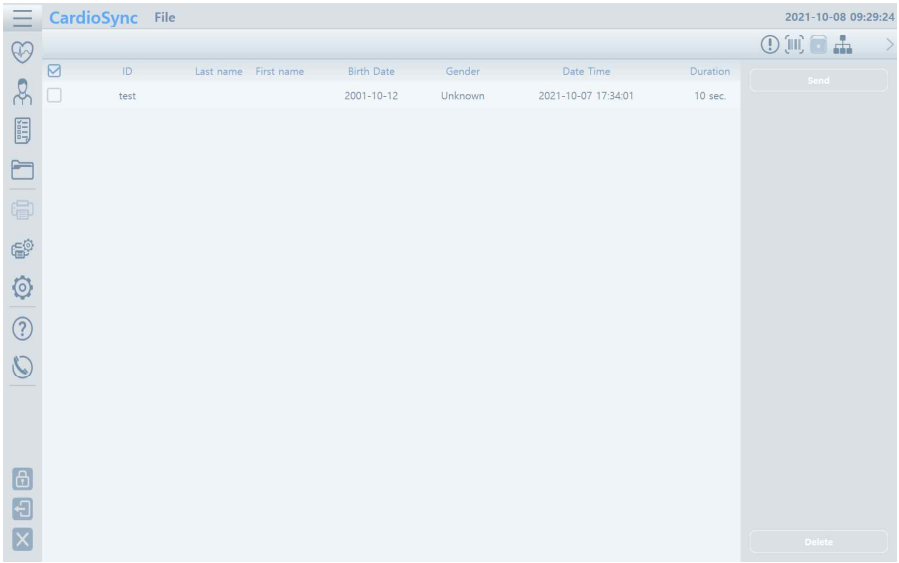
Specifies the center of the image in JPG, BMP format.

4) Transmit Data



It is available to send saved data out to connected external devices by using 'Export' button on the control panel on file screen.
If click 'Export' button on the control panel, selected data are sent. If failing to send data due to error in network while exporting, they are available to check on 'Retry Queue' screen.

Following is the main screen for 'Retry Queue.'

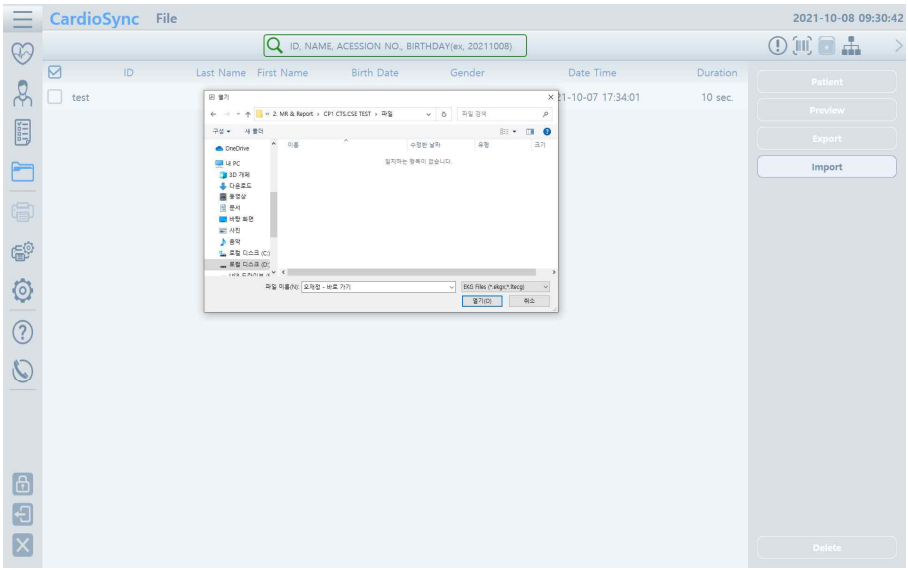


Files failed to be sent are indicated on 'Retry Queue' screen. Such files can be re-sent.

5) Import Data

It is available to import bionet format files saved on USB memory by using 'Import' button on the control panel from file screen.

If click 'Import' key on the control panel, following screen is shown.



If clicking 'open' button after selecting data to be loaded on the equipment, data can be loaded on the equipment.

Note
Only the files in following formats can be imported: ➔ ekgx, ltecg, stecg

Chapter 5. System Management

1) Maintenance and Cleanliness

Keep Cardio P1 equipment and handles clean. Avoid damaging or contaminating the equipment using the methods recommended below.
If you use the substances - including not allowed substances - that can damage on the product, warranty is not applied even during the warranty period.

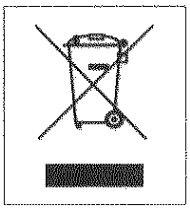
Note
Clean the equipment and examine the body and electrodes thoroughly. Do not use old or damaged equipment.

At least once a month, wipe the body and measuring electrodes with a soft cloth moistened with alcohol to keep them clean. Do not use lacquer, thinner, ethylene, or oxide. Keep cables and limb and chest electrodes free of dust and dirt, and wipe them with a cloth dampened in lukewarm water (40˚C/104˚F) after use. Wipe them with clinical grade alcohol at least once a week. Do not immerse equipment or ECG wires in liquids or detergents. Keep the equipment and cables away from liquids.

Note
If the equipment is determined to be visibly unclean at the end of the cleaning steps, you should repeat the relevant previous cleaning process.

Note
If the equipment experiences unacceptable deterioration, such as corrosion, discoloration, dents, or cracked seals, contact the seller where you purchased the equipment and follow his or her instructions whether to dispose of or repair it.

Existing Device Disposal



1. Products bearing this symbol (X-marked wheeled bins) are subject to European Directive 2002/96/EC.
2. All electrical and electronic products must be disposed of separately from municipal waste at the collection facility designated by government or local authorities.
3. Proper disposal of old devices helps prevent potential adverse consequences against environmental and human health.
4. For more information on the disposal of existing devices, contact City Hall, Waste Disposal Service Center, or the store where you purchased the product.

2) Regular Examination

As with any other medical equipment, have your Cardio P1 regularly safety inspected once a year. Refer to the service manual provided by Bionet for inspection items.

3) Simple Troubleshooting

- **When the signal is output with a lot of noise**
  : In this case, first check if the AC power filter is set. If there is still noise after setting, move the system to a power environment with less noise.

- **Cyber security Issues**
  1) If equipment is stolen or lost, contact the hospital staff or manufacturer as soon as possible.

     When a stolen or lost equipment report is filed, the hospital network administrator must take steps to prevent the equipment from accessing the hospital network.

  2) If a cyber security threat is detected while using the equipment, immediately disconnect it from the network and contact the hospital staff or manufacturer.

※ For manufacturer contact information, please refer to the table of contents of How to Contact Us.

System Message

ECG			
No.	**Message**	**Causes**	**Solution**
1	"Do you want to save new disclosure data from now? Click Yes to discard the old data and save the new one. Click No to continue saving following the previous data."	When data is stored in Disclosure, when there is existing data and a decision to process is required	Click 'Yes' if you want to delete existing data, or 'No' if you don't want to.

Patient			
No.	**Message**	**Causes**	**Solution**
1	Please fill the required fields.	When you click 'ok' without filling out the required fields when entering patient information	Retry after filling in required fields
2	Please fill the ID field.	When entering patient information and clicking 'OK' without filling in the ID field	Retry after filling in ID field
3	Invalid ID	In case of incorrect ID when entering patient information	Retry after entering the correct ID
4	The future cannot be set as the date of birth.	When entering a future date in 'Date of Birth' when entering patient information	Retry after checking the date
5	"All patient related information including study order and result will be deleted. Are you sure to continue?"	Confirmation procedure when deleting patient information	Click 'Yes' if you want to delete existing data, or 'No' if you don't want to.

File			
No.	**Message**	**Causes**	**Solution**
1	"The study record being exported will be discarded. Are you sure to continue?"	When the Cancel button is pressed when exporting a file	Click 'Yes' if you wish to cancel or 'No' if you do not wish to cancel.
2	Deleting old files to get more storage space.	Occurs when there is insufficient storage space in the computer	Retry after saving space
3	"There is a duplicate ID. Do you want to change it?"	If there is a duplicate ID when importing a file, check if you want to change it	Click 'Yes' if you want to change, click 'No' if you do not want to change
4	Not enough storage space. Please free up storage.	When there is no storage space for 'File' and 'Patient'	Retry after saving space
5	"The selected study record files will be deleted. Are you sure to continue?"	Confirmation procedure when deleting saved ECG files	Click 'Yes' if you want to delete existing data, or 'No' if you don't want to.

Worklist			
No.	**Message**	**Causes**	**Solution**
1	Are you sure to proceed to erase all user data?	When deleting data from worklist	Click 'Yes' if you want to delete or 'No' if you don't want to.
2	Fail to update worklist	In case of failure after updating in Worklist	If there is no information to update or an error has occurred, check, and retry

Setup			
No.	**Message**	**Causes**	**Solution**
1	Please check device AE title.	When device AE Title is entered incorrectly when setting PACS	Enter the correct value and try again
2	Please check device port.	When device port is entered incorrectly when setting up PACS	Enter the correct value and try again
3	Please check server AE title.	When the server AE Title is entered as an incorrect value when setting up PACS	Enter the correct value and try again
4	Please check server port.	When the server port is entered as an incorrect value when setting up PACS	Enter the correct value and try again
5	Echo failed.	In case of failure in PACS setting Echo Test	Check IP, AE Title or Port and try again
6	Echo succeeded.	If the Echo setting Ping Test is successful	
7	Ping failed.	In case of failure in PACS setup ping test	Check IP, AE Title or Port and try again
8	Ping succeeded.	If the PACS setting Ping Test is successful	
9	Please check the device (short)name.	When device (short)name is entered incorrectly when setting GDT	Enter the correct value and try again
10	Please check the GDT Server settings.	When there is a GDT setting error	Enter the correct value and try again
11	Please check your ID.	When ID is entered incorrectly when setting GDT	Enter the correct value and try again

12	Please check a import/export short name.	When setting GDT, when import/export short name is entered as an incorrect value	Enter the correct value and try again
13	Please check the shared folder.	When the shared folder is entered incorrectly when setting up the Web server	Enter the correct value and try again
14	Please check Web Server URL.	When URL information is entered as an incorrect value when setting up the Web Server	Enter the correct value and try again
15	Please check the user login name.	When ID is entered as an incorrect value when setting Web server, EMR/HIS	Enter the correct value and try again
16	Please check your password.	When the password is entered as an incorrect value when setting up the web server and EMR/HIS	Enter the correct value and try again
17	Verification failed.	Web Server, EMR/HIS linkage verification failed	In Web Server Setting, check URL, ID, and Password and retry. In EMR/HIS Setting, check Network Path, ID, and Password and retry.
18	Verification successful.	Confirmation success when interworking with Web Server and EMR/HIS	
19	Please check the Bionet WorlistCom's IP.	When Bionet WorlistCom's IP is entered incorrectly when setting EMR/HIS	Enter the correct value and try again
20	Please check server IP.	When the Server IP is entered as an incorrect value when setting EMR/HIS	Enter the correct value and try again
21	Please check the network path.	When Network Path is entered as an incorrect value when setting EMR/HIS	Enter the correct value and try again

22	The system erased all data.	When you click 'Delete all files' during factory reset	
23	Do you want to restore default settings?	Confirmation procedure when clicking 'Restore Default' during factory reset	Click 'Yes' if you agree or 'No' if you do not agree
24	The system is made into factory default.	Guidance message when trying to factory reset	
25	No printer configured! Please add a printer first in Printer Setup Page.	When setting up a printer, when no printer is configured	Retry after printer configuration
26	Your account has expired.	When the account registered in the user list has expired	Add a new account or extend the term

Others			
No.	**Message**	**Causes**	**Solution**
1	No search results	When there are no results when searching	Make sure you did your search correctly
2	Network error	In case the server setting is wrong or when the network connection is not possible	Retry after checking server settings or network
3	PDF view application is not installed.	When there is no pdf view application when viewing the manual	Retry after installing pdf view application

Please contact A/S center of our company if issue has not been solved with solution above.

4) Manufacturer Declaration

Electromagnetic Compatibility Information

Phenomenon	Basic EMC standard or test method	Test level/requirement
Mains terminal disturbance voltage	CISPR 11 EN 55011	Group1, Class A
Radiated disturbance	CISPR 11 EN 55011	Group1, Class A
Harmonic Current Emission	IEC 61000-3-2 EN 61000-3-2	Class A
Voltage change, Voltage fluctuations and Flicker Emission	IEC 61000-3-3 EN 61000-3-3	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	IEC 61000-4-2 EN 61000-4-2	±8 kV/Contact ±2, ±4, ±8, ±15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3 EN 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz, 10 Hz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3 EN 61000-4-3	Table 9 in IEC 60601-1-2: 2014
Electrical Fast Transient/Burst Immunity	IEC 61000-4-4 EN 61000-4-4	±2 kV, 100 kHz repetition frequency ±1 kV, 100 kHz repetition frequency
Surge Immunity	IEC 61000-4-5 EN 61000-4-5	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV

Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6 EN 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz, 10 Hz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8 EN 61000-4-8	30 A/m 50 Hz and 60 Hz
Voltage dips	IEC 61000-4-11 EN 61000-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		70 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11 EN 61000-4-11	0 % U_T; 250/300 cycle

Electromagnetic compatibility - Guidance and manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The Cardio P1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio P1 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Cardio P1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Cardio P1 is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage
Harmonic emissions IEC 61000-3-2	Class A	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Cardio P1 or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Cardio P1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio P1 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%UT (>95%dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5, 6 cycles 70 %UT (30 %dip in UT) for 25,30 cycles <5%UT (>95%dip in UT) for 5 s	<5%UT (>95%dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5, 6 cycles 70 %UT (30 %dip in UT) for 25,30 cycles <5%UT (>95%dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cardio P1 requires continued operation during power mains interruptions, it is recommended that the Cardio P1 be powered from an uninterruptible power supply or PC battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or
*Note: U_T is the AC voltage of the power before using test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Cardio P1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio P1 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the Cardio P1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is there commended separation distance in meters (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range. [b]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

			Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cardio P1 is used exceeds the applicable RF compliance level above, the Cardio P1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cardio P1.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the Cardio P1

The Cardio P1 is intended for use in an electromagnetic environment in which radiated RFdisturbances are controlled. The customer or the user of the Cardio P1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardio P1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz

	$d = [\frac{3,5}{V_1}]\sqrt{P}$	$d = [\frac{3,5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
	V1= 3 Vrms	E_1= 3 V/m	E1= 3 V/m
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Chapter 6. Product Specifications

ECG Leads	Simultaneous 12 channel ECG and acquisition
Recording Channel	3CH+3RHY, 3CH+1RHY, 6CH+1RHY, 12CH, 6CH+ST map 1CH Long Time (1min, 3min, 5min,10min, 20min, 30min) and Special Beat Report (Text, Guide, Vector, ST map)
Gain	2.5, 5, 10, 20, Auto (I~aVF: 10, V1~V6: 5) mm/mV
Printing Speed	5, 12.5, 25, 50, 100 mm/sec
Sampling Rate	Analysis Sampling Rate - 500Hz Digital Sampling Rate - 8,000Hz
Filters	AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better), Baseline Drift (0.05Hz, 0.1Hz, 0.2Hz, -3dB or better), Low Pass Filter(off, 40Hz, 100Hz, 150Hz)
Patient Data	ID, Name, Date of Birth, Age, Gender, Height, Weight, Race, Smoke, Department, Room No., Study Desc., Accession No., Referring Physician
Basic Measurement	Heart Rate (30~300bpm, ±3bpm), PR/RR Int, QRS Dur, QT/QTc Int, P-R-T axis, SV1/RV5/R+S Amp
Electrical	Internal Noise : 20uV(p-p)max Input Impedance : ≥ 50MΩ Input Voltage Range : ±5mV CMRR : > 105dB DC Offset Voltage : ≥ ±400mV Patient Leakage Current : < 10uA Frequency Response : 0.05~200 with in –3dB Isolated, Defibrillation and ESU Protected
Signal Quality Control	Pacemaker Pulse Detection Lead Fault Detection, Signal Saturation Detection
Input Power	5VDC (USB), Max. 0.5A
Communication	USB data communication (to PC)
Safety Conformity	Class I, Type CF applied parts: ECG electrodes

Environmental	**Operation**	Ambient Temperature : 10 to 40ºC Relative Humidity : 30 to 85% Atmospheric Pressure : 700 to 1060hPa
	Storage/Ship	Ambient Temperature : -20 to 60℃ Relative Humidity : 10 to 95% Atmospheric Pressure : 500 to 1060hPa
Dimensions		Body - 90.75(W) x 103.5(D) x 24.93(H)mm - Approx. 110g
Standard Accessory		Patient Cable (1EA), Limb Electrodes (1SET), Chest Electrodes (1SET), Power (USB Data) Cable (1EA), Hanger (1EA), Silicone Pad (1EA), ECG Gel (1EA) ECG Diagnosis Guide (1EA), USB Lock Key (1EA)

Warning
Do not touch patient cables or equipment when using a ventricular defibrillator.

Warning
When connecting electrodes or patient cables, do not allow connectors to touch conductive parts or ground. In particular, when attaching the electrodes to the patient's body, make sure that they do not come into contact with conductive parts or the ground.

Warning
Do not use the supplied ECG patient cables to measure respiration. They should be used for ECG measurement only.

Caution
For the electrode, use the same product as provided or a product with biocompatibility certified by international standards.

Caution
Cardio P1 should be used in the presence of a health care professional when used for patients who have undergone Cardiac Assist Device surgery.